

# ImmuCell

ImmuCell Corp

Ac/s  
P.E 12/31/01



02036638

## 2001 Annual Report

REC'D S.M.C.  
MAY 14 2002

ImmuCell  
**CALIFORNIA MASTITIS TEST KIT**



A rapid colorimetric test for early detection of bovine mastitis

CMT GeneMate  
Testing Podials  
Quadranting Bells



ImmuCell  
**BOVINE LEUKEMIA VIRUS ANTIBODY TEST KIT**

Tip-Test: BLV



A bovine serum or whole blood test for use on-site or in the laboratory  
Contains 10 tests

ImmuCell  
**MYCOBACTERIUM PARATUBERCULOSIS ANTIBODY TEST KIT**

Tip-Test: Johne's



A bovine serum or whole blood test for use on-site or in the laboratory  
Contains 25 tests



Confirm breeding heat  
Identify "open cows"  
Evaluate cycling activity

**ACCUFIRM**  
RAPID PROGESTERONE TEST KIT

**KAMAR**  
HEATMOUNT DETECTORS



ImmuCell  
**MASTITIS ANTIBIOTIC SUSCEPTIBILITY TEST KIT**

15 Tests  
Refrigerate MASTIK<sup>®</sup> Reagents: 35-45°F (2-7°C)  
Room temperature: 59-77°F (15-25°C)

Serial No.  
Expiration Date:

ANTIBIOTIC SUSCEPTIBILITY



A rapid in-vitro antibiotic susceptibility test for mastitis in the bovine  
Contains 15 Tests

PROCESSED  
MAY 20 2002  
THOMSON  
FINANCIAL P

ImmuCell  
**BOVINE CORONAVIRUS BOVINE ORIGIN**



**ESCHERICHIA COLI ANTIBODY**

First Defense

ImmuCell  
**BOVINE CORONAVIRUS-ESCHERICHIA COLI ANTIBODY BOVINE ORIGIN**



First Defense  
COLOSTRUM SUPPLEMENT

## *Letter to Our Shareholders*

I write this letter as we enter the fourth year of implementing our strategy focused on the developing, acquiring and marketing products that improve animal health and productivity in the dairy and beef industry. I am pleased to report that we are delivering on three important promises: grow revenues, sustain profitability and strengthen our commercial manufacturing capability. Product sales increased by the compound growth rate of 15% during this three-year period to \$6,395,000 for the year ended December 31, 2001. Our cumulative income before taxes for the three-year period ended December 31, 2001 aggregated \$1,724,000. We completed a 5,300 square foot addition to our facility enabling us to: a) increase production of **First Defense®** to clear the backlog of orders and b) bring the manufacture of **Wipe Out® Dairy Wipes** in-house.

The dairy and beef industry is a market that ImmuCell can serve well as we become a more market driven company. We understand the existing regulatory barriers and have the necessary manufacturing infrastructure to succeed. Our product development and acquisition activities support our marketing strategy. We can now leverage the sales of new products through the strong market position we have secured with **First Defense**. Through our new Intelligent Mastitis Management™ program, we offer the dairy practitioner and producer an integrated product line of disease prevention, diagnosis and treatment tools and promote a best practices approach to mastitis management.

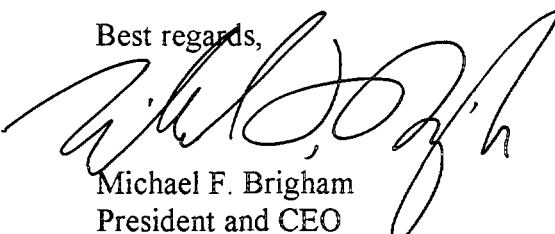
We believe that a measured investment in the research and development of new products is key to our future growth. Since mid 2000, the principal focus of our product development efforts has been **Mast Out™**, the application of Nisin as a mastitis treatment. Nisin, a natural anti-microbial protein, is the active ingredient in **Wipe Out**. **Mast Out** has the potential to offer dairy producers an alternative to antibiotics in the treatment of this very costly disease. We are preparing to conduct the pivotal field trials that are required to gain FDA approval of the product. Since March 2001, we have been awarded the aggregate of approximately \$927,000 in research funding, approximately \$666,000 of which funding is in support of the development of **Mast Out**. These grant awards represent a significant validation of the promise of our technology.

The 1999 acquisition of **Wipe Out** and the 2000 acquisition of the **MASTiK® Mastitis Antibiotic Susceptibility Test Kit** are examples of transactions that we can execute to expand our product offering to dairy and beef producers. We continue to look for similar products that fit our sales and marketing focus.

At the same time, we are working to realize value from and divest our non-animal health assets that were developed principally prior to 1999. In March 2001, we licensed certain DiffGAM rights to Novatreat Ltd of Finland. In August 2001, we sold an option to DMV International Nutritionals of the Netherlands to acquire our interest in AgriCell Company, LLC, our lactoferrin-producing joint venture.

We also hit an important growth milestone, that does not appear in our financial statements, when our employee count reached 30 in 2001. These highly dedicated people are the key to our future success. We appreciate the support of our shareholders and are committed to growing a successful company for the benefit of us all.

Best regards,



Michael F. Brigham  
President and CEO

FOR IMMEDIATE RELEASE:

April 22, 2002

**Contact:** Michael F. Brigham

President and Chief Executive Officer

(207) 878-2770 Ext. 3106

## **IMMUCELL ANNOUNCES 21% INCREASE IN SALES AND OTHER FIRST QUARTER 2002 RESULTS**

PORTLAND, Maine – April 22, 2002 -- **ImmuCell Corporation (NASDAQ/ICCC)** today announced the results of its operations for the three months ended March 31, 2002.

During the quarter ended March 31, 2002, total revenues increased by 27% to \$1,897,000 compared to the same period in 2001, while product sales increased by 21% to \$1,779,000. Research and development expenses increased by 21% to \$200,000, comprising 11% of total revenues during 2002. Net income increased by 46% to \$169,000, or \$0.06 per share, compared to net income of \$116,000, or \$0.04 per share, for the same period in 2001.

The Company's cash, cash equivalents and marketable securities increased to \$2,164,000 at March 31, 2002 as compared to \$1,883,000 at December 31, 2001. Total assets increased to \$7,434,000 at March 31, 2002 from \$7,117,000 at December 31, 2001. The Company's net working capital increased to \$3,310,000 at March 31, 2002 from \$2,943,000 at December 31, 2001. Stockholders' equity increased to \$6,237,000 at March 31, 2002 from \$6,046,000 at December 31, 2001.

"These solid results help us begin the fourth year of implementing our strategy focused on developing, acquiring and marketing products that improve animal health and productivity in the dairy and beef industry," commented Michael F. Brigham, president and chief executive officer. "Product sales were limited in the first quarter of 2001 due to the backlog of First Defense® orders worth approximately \$1,000,000 as of March 31, 2001, compared to no backlog of orders as of March 31, 2002."

ImmuCell Corporation is a biotechnology company dedicated to benefiting its employees and shareholders through innovative and proprietary products that improve animal health and productivity in the dairy and beef industry. In addition to operating a growing and profitable animal health business, the Company has demonstrated preliminary efficacy in an open label, Phase I/II efficacy study of DiffGAM, an alternative to antibiotics in the treatment and/or prevention of *Clostridium difficile*-associated diarrhea in humans. Certain nutritional rights to the DiffGAM technology have been licensed to a corporate partner.

###MORE###

ImmuCell Corporation

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Telephone (207) 878-2770 • Telefax (207) 878-2117  
[www.ImmuCell.com](http://www.ImmuCell.com)

IMMUCELL CORPORATION  
RESULTS OF OPERATIONS

EARNINGS (In thousands, except per share amounts)	(Unaudited) Three Months Ended	
	<u>March 31,</u>	
	<u>2001</u>	<u>2002</u>
Total revenues	\$ 1,489	\$ 1,897
Product sales	1,470	1,779
Research and development expenses	165	200
Income before taxes	193	287
Tax expense	77	118
Net income	\$ 116	\$ 169
Net income per common share:		
Basic	\$ 0.04	\$ 0.06
Diluted	\$ 0.04	\$ 0.06
Weighted average common Shares outstanding during period:		
Basic	2,714	2,734
Diluted	2,814	2,883

## BALANCE SHEET HIGHLIGHTS

(In thousands)	(Unaudited)	
	<u>December 31, 2001</u>	<u>March 31, 2002</u>
Cash, cash equivalents and marketable securities	\$ 1,883	\$ 2,164
Total assets	7,117	7,434
Net working capital	2,943	3,310
Long term bank debt	392	386
Stockholders' equity	\$ 6,046	\$ 6,237

ImmuCell Corporation press releases and other information about the Company are available at its corporate web site at <http://www.ImmuCell.com>.

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2001

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

0-15507  
(Commission file number)

**IMMUCELL CORPORATION**

(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

01-0382980  
(I.R.S. Employer  
Identification No.)

56 Evergreen Drive, Portland, Maine  
(Address of principal executive offices)

04103  
(Zip Code)

Registrant's telephone number, including area code: (207) 878-2770

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12 (g) of the Act: Common Stock par value \$.10 per share  
(Title of class)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

The aggregate market value of the Common Stock held by non-affiliates of the Registrant at March 20, 2002 was approximately \$7,069,000.

The number of shares of the Registrant's Common Stock outstanding at March 20, 2002 was 2,735,984.

Documents incorporated by reference: Portions of the Registrant's 2002 Proxy Statement to be filed in connection with the Annual Meeting of shareholders are incorporated by reference to Part III hereof.

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### *SIGNATURES*

## PART I

### ITEM 1 - BUSINESS

#### *General*

ImmuCell Corporation (the "Company") is a biotechnology company dedicated to producing innovative and proprietary products that improve animal health and productivity in the dairy and beef industry. During 2001, the Company invested in an addition to its facility in Portland, Maine and the necessary manufacturing equipment to expand production of First Defense® and to bring the production of Wipe Out® Dairy Wipes in-house. Also during 2001, the Company made progress in its on-going efforts to realize value from and divest its non-animal health related assets by licensing certain nutritional rights to its DiffGAM technology to an outside party and by entering into an option agreement to sell its ownership interest in its lactoferrin producing joint venture.

From its inception in 1982, the Company has engaged in the research and development of infectious disease diagnostic tests and products for therapeutic and preventive use against certain infectious diseases in animals and humans. Prior to 1999, the Company invested significant funds in the development of products utilizing its core technologies for human health product applications. Since 1999, the Company has focused the majority of its product development efforts on animal health products for the dairy and beef industry. Research and development expenses amounted to 16% and 13% of total revenues in 2000 and 2001, respectively. Internally funded research and development expenses (those expenses not supported by outside sources of funding such as grant and technology licensing income) amounted to 15% and 10% of product sales in 2000 and 2001, respectively. Initiated in 2000, the Company's primary research and development program is the application of Nisin as an alternative to antibiotics in the treatment of mastitis in dairy cows. The Company intends to continue to partially offset the cost of its research and development efforts through government grants. When product sales increase, the Company can reduce the ratio of internally funded research and development expenses to sales, while not materially decreasing the absolute dollar value of the investment in product development.

One result of this shift in strategic focus to animal health products, which are generally less expensive to develop than human health products, is that the Company was able to record consecutive net income for each of the three years ended December 31, 2001. Product sales increased by \$910,000, an increase of 17%, to \$6,395,000 for the year ended December 31, 2001. The compound growth rate of product sales for the three years ended December 31, 2001 was 15%.

While working to minimize deviations from its animal health objectives, the Company continues to seek a return on the research and development efforts made principally prior to 1999 in four ways: 1) earning royalty income from the application of its milk protein purification technology to the production of whey protein isolate, 2) achieving a return on its investment in Crypto-Scan®, 3) licensing rights to DiffGAM to a partner and 4) selling its ownership interest in its joint venture that utilizes its milk protein purification technology to produce lactoferrin.

#### *Animal Health Products for the Dairy and Beef Industry*

In December 2001, the Company obtained approval from the U.S. Department of Agriculture ("USDA") to sell Tip-Test®: BLV, which is a rapid, on-site immunodiagnostic test for the detection of Bovine Leukemia Virus ("BLV") infections. BLV is a highly prevalent disease in U.S. dairy and beef herds and can cause Leukosis, a severe and often fatal complication in a small percentage of cattle infected with BLV. This highly sensitive and specific product delivers on-site results from a blood or serum sample in about twenty minutes, which is a significant advantage to dairy and beef producers in comparison to the existing diagnostic technology that is performed in centralized laboratories.

In early 2001, the Company initiated commercial sales of its internally developed California Mastitis Test ("CMT"). This test can be performed cow-side for early detection of mastitis (inflammation of the mammary gland). CMT was developed for individual cow and bulk tank somatic cell monitoring.

In December 2000, the Company acquired the product MASTiK®, Mastitis Antibiotic Susceptibility Test Kit, from Lotek, Inc. of Pomfret Center, Connecticut. The Company paid \$35,000 on closing for the rights to this product and related patent and paid an additional \$40,000 in July 2001 to maintain ownership of the product. MASTiK helps veterinarians and dairy producers quickly select the antibiotic most likely to be effective in the treatment of individual cases of mastitis. MASTiK can usually provide this answer in less than one day, which is dramatically faster than the other commonly used antibiotic susceptibility tests.



In December 1999, the Company acquired rights to the product Wipe Out® Dairy Wipes and certain other related rights from Nutrition 21, Inc. (formerly AMBI Inc.) of Purchase, New York. The transaction included the purchase of certain equipment, trademarks and a license of intellectual property for an aggregate of \$359,000. The Company also acquired approximately \$173,000 of product inventory. The Wipe Out product consists of pre-moistened towelettes that are impregnated with Nisin to clean, sanitize and dry the teat area of a cow in advance of milking. Nisin is a natural antibacterial protein that has been demonstrated in clinical studies to be an effective aid in the reduction of disease-causing organisms in dairy cows. The use of Nisin for such applications is covered by five issued patents that were licensed by Nutrition 21 to the Company.

In December 1999, the Company also obtained approval from the USDA to sell Tip-Test®: Johne's, which is a rapid immunodiagnostic test for the detection of Johne's disease, a chronic intestinal infection of cattle caused by *Mycobacterium avium* subspecies *paratuberculosis*. This highly sensitive product delivers on-site results from a blood or serum sample in about twenty minutes, which is a significant advantage to dairy and beef producers in comparison to the existing diagnostic technology that is performed only in certified veterinary diagnostic laboratories (which is a more time consuming and expensive process). Before sales can be initiated in any state, the USDA approval is subject to the further approval of each state veterinarian. The Company has obtained the necessary state approval in many states and is proceeding to obtain the necessary approvals throughout the U.S. market.

In 1991, the Company obtained approval from the USDA to sell First Defense®, which is manufactured by the Company from cows' colostrum using the Company's proprietary vaccine and milk protein purification technologies. Currently, First Defense is the only USDA-licensed, bivalent (effective in combating two different infectious agents) scours preventive product on the market. The target disease, "calf scours", is seasonal, with the highest incidence in the winter calving months. This disease causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death.

In 1988, the Company entered into an exclusive world-wide license to purchase from Kamar, Inc. of Steamboat Springs, Colorado and to market and sell an animal health care product known as the Kamar® Heatmount® Detector. This product is used to detect the physical mounting of bovines for the determination of standing heat, and is sold primarily to dairy farmers. In 1998, the Company entered into a renewal of its service and license agreement effective through December 31, 2003 with Kamar whereby Kamar will continue to provide the Company warehousing, distribution and certain other services and the Company will continue to market the Kamar Heatmount Detector under the exclusive world-wide license. The renewal agreement was initially cancelable by either party upon twelve months written notice. In September 2000, this license was extended by one year to December 31, 2004, and the right of Kamar to cancel early without cause was eliminated. In connection with this extension, the Company began to transition marketing responsibilities for this product back to Kamar. A former officer of the Company was hired by Kamar Products, LLC to direct certain marketing efforts for this product going forward in anticipation of the expiration of the license on December 31, 2004.

The Company also markets the following two animal health products: 1) RPT™ and Accufirm™, trade names for a milk progesterone test used by dairy farmers to monitor the reproductive status of their cows and 2) RJT™, used in the detection of Johne's disease. Sales of these products have been limited since their commercial introductions. The sales and sales growth potential for these products in the future are not expected to be significant.

#### *Other Animal Health Products*

While the Company continues its efforts with internally and externally funded product development programs, the Company is also actively seeking to acquire new products and technologies that fit with the Company's marketing focus on the dairy and beef industry.

#### *Sales and Marketing*

The Company engages in the direct marketing and sales of its products principally through its wholly-owned marketing subsidiary, the Kamar Marketing Group, Inc. The manner in which the Company's products are marketed and distributed depends in large measure upon the nature of the particular product, its intended users and the country where it is sold. The distribution channel selected is intended to address the particular characteristics of the marketplace for a given product. First Defense is primarily sold through major veterinarian distributors, and the Kamar Heatmount Detector is sold through bovine semen distributors and farm supply retailers. Separate agreements have been entered into for sales through these distribution channels. Beginning in October 2000, a significant portion of the sales and

marketing effort for the Kamar® Heatmount® Detector was transitioned back to Kamar, funded by the royalty on sales paid by the Company to Kamar. The Company sells Wipe Out® Dairy Wipes directly to the dairy producer. The two Tip-Test® products, MASTiK® and CMT are sold principally to bovine veterinarians.

The Company is a leader in the scours (diarrhea) prevention market with its product First Defense®. With the acquisition of Wipe Out Dairy Wipes, the Company entered the mastitis market, which disease costs the U.S. dairy industry an estimated \$1 to \$2 billion per year. Under its Intelligent Mastitis Management™ program, the Company intends to coordinate its efforts in this disease area and add value to dairy producers by offering a range of useful products. Wipe Out helps prevent the infection, the Company's California Mastitis Test is used to determine which quarter is infected with mastitis and MASTiK helps the producer select the most effective antibiotic to help treat it. In addition, the Company is in the process of developing Mast Out™, a Nisin-based treatment for mastitis as an alternative to antibiotics. The commercial introduction of this product is subject to approval by the U.S. Food and Drug Administration ("FDA"). The U.S. market for products in this category in lactating cows is estimated at \$20,000,000 per year. Tip-Test: Johne's and Tip-Test: BLV comprise the Company's line of on-site infectious disease diagnostic products.

The Company spent 18% and 21% of product sales on sales and marketing expenses in the years ended December 31, 2000 and 2001, respectively. Going forward, the Company expects to invest slightly more than 20% of product sales in selling expenses as it launches new products and initiates new product sales.

#### *Foreign Sales*

Foreign product sales represented approximately 24%, 22% and 22% of the Company's total product sales for the years ended December 31, 1999, 2000 and 2001, respectively. The majority of these foreign sales were to Canada, Australia, New Zealand and European countries. It is anticipated that a significant amount of the Company's future sales will continue to be made outside of the United States.

With the exception of Australia and New Zealand, the Company currently prices most of its products in U.S. dollars. An increase in the value of the dollar in any foreign country in which the Company's products are sold may have the effect of increasing the local price of such products, thereby leading to a reduction in demand. Price adjustments have been made on occasion to mitigate these effects. Such a negative impact of the strong U.S. dollar was experienced in sales to Pacific rim countries. On the other hand, to the extent that the value of the dollar may decline with respect to a foreign currency, the Company's competitive position may be enhanced.

#### *Research and Development*

Beginning in 1998, the Company shifted the primary focus of its research and development efforts to products for the dairy and beef industry. This focus continued through 2001 and is expected to continue in 2002 and beyond. To expand its commercialized line of products for use by dairy and beef producers, the Company continues to invest in the development of new diagnostic products leveraging the Company's experience with infectious diseases. The Company also is investing in development programs of certain disease treatment and preventive products.

In April 2000, the Company acquired an exclusive license to develop and market Nisin-based products for animal health applications from Nutrition 21, Inc. Nisin is a bacteriocin with activity against gram positive and some gram negative bacteria. The lead application of this technology being developed by the Company is an intramammary infusion product to treat mastitis. The Company intends to market this product under the Mast Out brand name if regulatory approval from the FDA is obtained. Mast Out could prove to be a much needed alternative to the current use of antibiotics in the treatment of mastitis. Antibiotic use forces producers to discard milk during the course of antibiotic treatment and contributes to the growing concern about overuse of antibiotics in food animals.

The Company maintains relationships with several scientific advisors that have particular expertise in the areas targeted by the Company. The Company's research and development activities are conducted internally and through contracts with third parties depending upon the availability of staff, the technical skills required, the nature of the particular project and other considerations. As additional opportunities to commercialize the Company's technology become apparent, the Company may begin new research and development projects. The Company spent approximately \$813,000, \$922,000 and \$849,000 on research and development activities during the years ended December 31, 1999, 2000 and 2001, respectively. These expenditures were in part supported by grant and technology licensing income totaling approximately \$187,000, \$96,000 and \$178,000 during the years ended December 31, 1999, 2000 and 2001, respectively.

## Competition

The Company's competition in the animal health market includes other biotechnology companies and major animal health companies. Many of these competitors have substantially greater financial, marketing, manufacturing and human resources and more extensive research and development facilities than the Company. Many of these competitors may develop technologies and/or products which are superior to those of the Company, or may be more successful in developing production capability or in obtaining required regulatory approvals. The Company believes that First Defense® offers two significant competitive advantages over other products in the market: 1) its capsule form, which does not require refrigeration and provides ease of administration and 2) competitive products currently on the market provide protection only against one leading cause of calf scours (*E. coli*), while First Defense provides this protection and additional protection against another leading cause of the disease (coronavirus). Competitive companies have introduced products similar to the Kamar® Heatmount® Detector, and the success of these products could reduce sales of the Kamar Heatmount Detector.

The Company believes that its competitive position will be highly influenced by its ability to attract and retain key scientific and managerial personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products and to continue to profitably sell its current products. The Company currently competes on the basis of product performance, price and distribution capability. The Company continues to monitor its network of independent distributors to maintain its competitive position.

The Company believes that supplies and raw materials for the production of its products are readily available from a number of vendors and farms. It is the Company's policy to maintain several sources of supply for the components used in the Company's products.

### *Milk Antibody Product Under Development For Humans*

In addition to operating a growing and profitable animal health business, the Company has demonstrated preliminary efficacy in an open label, Phase I/II efficacy study of DiffGAM, a safe alternative to antibiotics in the treatment and/or prevention of *Clostridium difficile*-associated diarrhea ("CDAD") in humans. DiffGAM bovine anti-*Clostridium difficile* immunoglobulins is a bovine milk-derived specific polyclonal antibody product, which is subject to approval by the FDA before sales could be initiated. CDAD is caused by toxin-producing *Clostridium difficile*. DiffGAM is intended to neutralize the toxins produced by *Clostridium difficile* in the colons of affected patients. CDAD is caused most frequently by the use of broad spectrum oral antibiotics, which kill bacteria in the colon that normally inhibit the proliferation of *Clostridium difficile*. When *Clostridium difficile* then proliferates, producing toxins that cause disease, the standard treatment is to use oral antibiotics specific for *Clostridium difficile*. This multi-antibiotic treatment approach can lead to high rates of relapse and the development of antibiotic resistance.

The Company has developed a proprietary formulation to deliver active antibodies to the lower gastrointestinal tract, the site of *Clostridium difficile* infections. The Company believes that this formulation is central to the effectiveness of DiffGAM. The Company's proprietary milk protein purification technology is used to manufacture DiffGAM and the Company's commercialized animal health product, First Defense.

Under an Investigational New Drug application filed with the FDA in March 1997, a clinical trial was conducted in mid-1997 demonstrating the safety of DiffGAM and the colonic bioavailability of the patented oral formulation of the product. The Company completed a multi-site Phase I/II clinical trial of this product in 2000. The results of this trial demonstrated the safety and preliminary effectiveness of DiffGAM in the treatment of established CDAD. The Company is seeking a partner to fund further development activities in exchange for marketing rights to the product. The Company would expect to benefit from a manufacturing and supply arrangement with such a partner. The Company does not intend to further fund this product development internally.

Clinical development of a second product, TravelGAM bovine anti-*E. coli* immunoglobulins, was discontinued in 1998. TravelGAM was intended to prevent diarrhea caused by enterotoxigenic *E. coli* (commonly known as Travelers' Diarrhea). Further development of this product was discontinued principally due to the lack of a detectable treatment effect in field trials despite the more positive results from earlier hospital-based trials. Clinical development of a third product, CryptoGAM bovine anti-*Cryptosporidium* immunoglobulins, was discontinued in 1997. CryptoGAM was intended to treat chronic, life-threatening diarrhea (known as cryptosporidiosis) in AIDS patients. The decision to discontinue development was made principally because the targeted patient population for the product had materially decreased due to the positive impact of new drug therapies on AIDS patients.

In March 2001, the Company licensed certain rights for nutritional, risk reduction applications of the DiffGAM technology outside of North America to Novatreat Ltd of Turku, Finland. The Company received \$100,000 during 2001 in connection with the initial supply of clinical material to Novatreat under the license and supply agreement. This technology licensing income is being recognized over the twenty-two month period ending in December 2002. Novatreat is responsible for the necessary product development, clinical trial and regulatory costs going forward. Beginning in 2003 and thereafter, the Company expects to earn a manufacturing gross margin and royalties on product sales under the long-term supply component of the agreement. Product ordered by Novatreat will be manufactured at the Company's plant. The license agreement does not cover the pharmaceutical applications of the Company's colonic delivery or milk processing intellectual property. The Company is currently seeking to license the North American nutritional rights and the world-wide pharmaceutical rights to the DiffGAM technology to one or more additional outside parties.

Since 1990, the Company has received four Phase I and three Phase II Small Business Innovation Research grants from the National Institutes of Health to support the development of milk antibody products to prevent gastrointestinal infections in humans. The value of these grants has aggregated approximately \$1,891,000 since 1990, the final \$66,000 of which funding was recognized during the year ended December 31, 2000.

#### *Product to Detect Cryptosporidium in Drinking Water*

Capitalizing on certain scientific knowledge gained under the Company's CryptoGAM research program described above, the Company developed Crypto-Scan® water diagnostic test. This non-animal health product utilizes the Company's immunomagnetic separation ("IMS") technology. During 1997, the Company entered into a distribution agreement with Adreck Marketing Limited covering sales in the United Kingdom, which the Company allowed to expire as of December 31, 2001. The Company is currently seeking a buyer for this product and the related technology. Initial sales in the U.K. were limited as the Company worked to gain access to the market through the applicable U.K. regulatory authorities. Crypto-Scan was approved by the U.K. regulatory authority in November 2000. Subsequent to the regulatory approval of this product, additional regulatory requirements were imposed by the U.K regulatory authorities that require that each user of a new product be individually validated by such authorities before using a new product in regulated testing procedures. Sales in the U.S. market would be influenced significantly by the policies of the U.S. Environmental Protection Agency.

#### *Commercialization of Milk Protein Purification Technology for Nutritional Applications*

Underlying the Company's milk antibody products for animal and human health applications is a certain expertise developed by the Company to process and purify milk proteins. The Company is realizing a return on two non-animal health applications of this technology through licensing arrangements with companies that are strategically focused on selling products to the applicable human markets.

In 1996 the Company formed a joint venture with Agri-Mark Inc. of Methuen, Massachusetts known as AgriCell Company, LLC to produce and sell a nutritional protein derived from cheese whey, known as lactoferrin. Lactoferrin is an iron-binding protein that, among several applications, can be used in infant formula, nutritional applications and certain cosmetics. The Company licensed certain rights to a patented purification system to AgriCell for use in the production of lactoferrin. In 1997, AgriCell commissioned a 6,800 square foot production facility at Agri-Mark's cheese plant in Middlebury, Vermont which was subsequently approved by the USDA, allowing the commercial production of lactoferrin to be initiated. Initial sales of lactoferrin have been limited, and the operations of the joint venture have not been profitable. The Company has a 50% ownership interest in this joint venture and is entitled to 50% of the joint venture's profits after Agri-Mark has obtained the return of an amount equal to its invested capital. Agri-Mark funded a capital investment by AgriCell in excess of \$1,000,000 principally in working capital, fixed assets and production facility modifications, and Agri-Mark is entitled to a 90% priority return until it obtains the return of an amount equal to this invested capital. Additionally, Agri-Mark has the right to utilize the Company's technology to produce and sell whey protein isolate from Agri-Mark's Vermont cheese whey source. The Company is entitled to a royalty on any such sales.

In August 2001, the Company entered into an option agreement under which DMV International Nutritionals of the Netherlands paid the Company \$100,000 for an option to buy the Company's interest in this joint venture. The \$100,000 from this sale of an option to the technology is being recognized over the twenty month period ending in March 2003. DMV can exercise the option on or before March 2003 by paying the Company \$1,300,000 for its interest in the joint venture. DMV is principally funding the operations of the joint venture during the option period.

In 1997, the Company licensed certain rights to the same patented protein purification system described above to Murray Goulburn Co-operative Co., Limited of Australia for the production of whey protein isolate and certain other milk proteins (excluding high purity lactoferrin). In consideration for the license, the Company received a \$250,000 payment in 1997 and is entitled to a royalty on the sales of whey protein isolate and any other milk proteins manufactured under this license. In early 2000, Murray Goulburn launched commercial sales of whey protein isolate. Approximately \$55,000 and \$79,000 in royalty income was earned by the Company in 2000 and 2001, respectively.

#### *Skin and Environment Sanitizing Products*

In connection with the December 1999 acquisition of Wipe Out® Dairy Wipes, the Company acquired exclusive rights to develop Nisin as a skin and environment sanitizer. While these potential products are not directly related to the Company's animal health marketing focus, the Company intends to attempt to benefit from the expertise being developed in the manufacture of Nisin for its animal health products, Wipe Out and Mast Out™. While there is significant published scientific literature that evidences the broad-spectrum, antimicrobial activity of Nisin, the Company has no intention or right to pursue medical claims for any human skin sanitizing products.

In February 2002, the Company was awarded a one-year grant aggregating \$191,000 from the National Institutes of Health to fund certain applications of this technology. Under this grant and in collaboration with Clemson University, the Company intends to investigate the effectiveness of Nisin alone and in combination with another bacteriocin as a topical skin sanitizer.

#### *Patents and Proprietary Information*

In 1998, the Company was issued U.S. Patent No. 5,747,031, covering certain aspects of the Company's proprietary manufacturing process to separate antibodies from cows' milk used in the production of DiffGAM. In June 2000, the Company was issued U.S. Patent No. 6,074,689 covering the method of formulation responsible for colonic delivery in DiffGAM and for other proteins. In 1999, the Company obtained an exclusive license for pharmaceutical applications to U.S. Patent No. 5,773,000 entitled "Therapeutic Treatment of *Clostridium difficile* Associated Diseases" from GalaGen, Inc. In connection with this license, the Company agreed to pay GalaGen a royalty on any related product sales.

In connection with the December 1999 acquisition of Wipe Out Dairy Wipes, the Company acquired a license to several patents covering the use of Nisin in antimicrobial wipes as well as certain proprietary know-how used in the production of Nisin from Nutrition 21, Inc. In April 2000, the Company acquired an additional license to several patents covering the use of Nisin in specific antimicrobial formulations in the veterinary field of use from Nutrition 21. The Company also has exclusive license rights to certain cloned antigens of *Cryptosporidium parvum* from the Regents of the University of California, for which two U.S. patents have been issued to the Regents. This license covers vaccine product applications for animals and was sublicensed by the Company exclusively to AgriVax Inc. in 1999 in return for a royalty on any product sales. In conjunction with the December 2000 acquisition of MASTIK®, the Company acquired the related U.S. Patent No. 5,026,638 covering the test procedure.

Going forward, the Company may file additional patent applications for certain products under development. There can be no assurance that patents will be issued with respect to any pending or future applications.

In some cases, the Company has chosen and may choose in the future not to seek patent protection for certain products or processes. Instead, the Company has sought and may seek in the future to maintain the confidentiality of any relevant proprietary technology through contractual agreements. Reliance upon trade secret, rather than patent protection, may cause the Company to be vulnerable to competitors who successfully replicate the Company's manufacturing techniques and processes. Additionally, there can be no assurance that others may not independently develop similar trade secrets or technology or obtain access to the Company's unpatented trade secrets or proprietary technology. All of the Company's employees are required to execute nondisclosure and invention assignment agreements designed to protect the Company's rights in its proprietary products.

Other companies may have filed patent applications and may have been issued patents involving products or technologies potentially useful to the Company or necessary for the Company to commercialize its products or achieve its business goals. There can be no assurance that the Company will be able to obtain licenses to such patents on terms acceptable to the Company.

## *Trademarks*

The Company has registered certain trademarks with the U.S. Patent and Trademark Office in connection with the marketing of its products. The Company has obtained federal trademark registration of the following trademarks: First Defense®, for one of its animal health products, Crypto-Scan®, for its water diagnostic test, Tip-Test®, for its on-site diagnostic product line, and MASTiK®, for its antibiotic susceptibility test. In addition, the Company markets two bovine products under the following trademarks: RPT™, Accufirm™ and RJT™. In December 1999, the Company purchased the federal trademark application for Wipe Out® and related design and the registered trademark, the "One Step Cow Prep®". In September 2000, the Company received U.S. registration #2,385,820 for Wipe Out, and in November 2000, the Company received U.S. registration #2,406,502 for the related design. In November 2001, the Company received a notice of allowance for the trademark Mast Out™.

## *Government Regulation*

The manufacture and sale of some of the Company's animal health products within the United States is regulated by the USDA. The manufacture and sale of disease treatment and prevention products for human health applications and for certain animal health products within the United States is subject to regulation by the FDA. Comparable agencies exist in foreign countries and foreign sales of the Company's products will be subject to regulation by such agencies. Many states (including Maine where the Company's facilities are located) have laws regulating the production, sale, distribution or use of biological products, and the Company may have to obtain approvals from regulatory authorities in states in which it proposes to sell its products. Depending upon the product and its applications, obtaining USDA and other regulatory approvals may be a relatively brief and inexpensive procedure or it may involve extensive clinical tests, incurring significant expenses and an approval process of several years' duration.

The Company has received USDA approval for Tip-Test: BLV (its on-site Bovine Leukemia Virus diagnostic test), Tip-Test: Johnne's (its on-site Johnne's disease diagnostic test), First Defense (its scours preventive product) and RJT (its Johnne's disease diagnostic test). The Company completed an FDA Phase I/II clinical trial of DiffGAM (to prevent *Clostridium difficile*-associated diarrhea) under an approved Investigational New Drug application. Regulatory approval of Crypto-Scan from the Drinking Water Inspectorate in the United Kingdom was obtained in November 2000. The Company believes that it is in compliance with current regulatory requirements relating to the Company's business and products.

## *Product Liability*

The manufacture and sale of certain of the Company's products entails a risk of product liability. The Company's current exposure to product liability is mitigated to some extent by the fact that the Company's current products have heretofore been principally directed towards the animal health market. The Company has maintained product liability insurance in an amount which it believes is adequate to cover its potential exposure in this area.

## *Employees*

The Company and its wholly-owned subsidiary, the Kamar Marketing Group, Inc., currently employ approximately thirty employees, including two part-time employees. The full-time equivalent of approximately fourteen employees are engaged in manufacturing operations, seven in research and development activities, four in finance and administration and four in marketing and sales. The manufacturing personnel are also utilized, as needed, in the production of clinical material for use in research and development. The Company is not a party to any collective bargaining agreement and considers its employee relations to be excellent.

## **ITEM 2 - PROPERTIES**

The Company owns a 15,300 square foot building at 56 Evergreen Drive in Portland, Maine. The Company currently uses this space for substantially all of its office, laboratory and manufacturing needs. A construction project that added approximately 5,300 square feet of new manufacturing space to the original 10,000 square foot building to increase the production capacity of First Defense and to provide in-house production capability for Wipe Out Dairy Wipes was completed in May 2001. The facility addition also includes a storage mezzanine of approximately 2,000 square feet. In addition, the building has 5,000 square feet of unfinished space available for potential future expansion on the second floor.

The Company also maintains access to certain animals, primarily cows, through contractual relationships with several farms.

### ITEM 3 - LEGAL PROCEEDINGS

None

### ITEM 4 - SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

## PART II

### ITEM 5 - MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

The Company's common stock trades on The Nasdaq SmallCap Market tier of The Nasdaq Stock Market under the symbol: ICCC. No dividends have been declared or paid on the common stock since its inception, and the Company does not contemplate the payment of cash dividends in the foreseeable future.

The following table sets forth the high and low sales price information for the Company's common stock as reported by The Nasdaq Stock Market during the period January 1, 2000 through December 31, 2001:

	2000				2001			
	<u>1st Qtr.</u>	<u>2nd Qtr.</u>	<u>3rd Qtr.</u>	<u>4th Qtr.</u>	<u>1st Qtr.</u>	<u>2nd Qtr.</u>	<u>3rd Qtr.</u>	<u>4th Qtr.</u>
High	\$9.97	\$5.31	\$4.25	\$2.75	\$3.13	\$3.00	\$3.00	\$5.75
Low	\$2.41	\$2.50	\$2.25	\$1.50	\$1.58	\$2.40	\$2.25	\$2.75

As of March 20, 2002, the Company had 8,000,000 common shares authorized and 2,735,984 common shares outstanding, and there were approximately 1,300 shareholders of record. The last sales price of the Company's common stock on March 20, 2002 was \$3.12 as quoted on The Nasdaq Stock Market.

### ITEM 6 - SELECTED FINANCIAL DATA

The selected financial data set forth below has been derived from the audited financial statements of the Company. The information should be read in conjunction with the audited financial statements and related notes appearing elsewhere in this Form 10-K.

	Year Ended December 31,				
	1997	1998	1999	2000	2001
Statement of Operations Data:					
Total revenues	\$4,556,678	\$4,481,867	\$4,909,245	\$5,635,985	\$6,676,766
Product sales	3,982,789	4,199,851	4,722,374	5,485,003	6,395,140
Research & development expenses	1,068,069	1,012,813	812,892	922,347	849,174
Net profit (loss) before taxes	263,852	(102,518)	550,843	475,888	697,040
Net profit (loss) after taxes	263,852	(102,518)	550,843	2,222,046	420,435
Per Common Share:					
Basic net profit (loss)	0.11	(0.04)	0.23	0.84	0.15
Diluted net profit (loss)	0.10	(0.04)	0.22	0.79	0.15
Stockholders' equity	0.96	0.93	1.15	2.08	2.22
Cash dividend	--	--	--	--	--
Statement of Cash Flows Data:					
Net cash provided by operating activities	103,891	639,821	679,699	81,505	905,757
Balance Sheet Data:					
Total assets	3,231,050	3,144,847	3,855,979	6,443,916	7,117,217
Cash, cash equivalents and short term investments	1,021,324	1,538,905	1,823,689	1,895,149	1,883,090
Current liabilities	561,795	443,902	605,923	490,745	564,432
Net working capital	1,642,363	1,866,222	2,219,386	2,894,249	2,942,658
Long-term liabilities	339,747	453,349	434,658	414,178	507,131
Stockholders' equity	\$2,329,508	\$2,247,596	\$2,815,398	\$5,538,993	\$6,045,654

## ITEM 7 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Results of Operations

#### *Fiscal 2001 Compared to Fiscal 2000*

Total revenues for the year ended December 31, 2001 increased by \$1,041,000 (18%) to \$6,677,000 from \$5,636,000 in 2000. Product sales for the year ended December 31, 2001 increased by \$910,000 (17%) to \$6,395,000 from \$5,485,000 in 2000. Product selling prices have generally increased in line with inflation. Grant income increased by \$36,000 (38%) to \$133,000 in 2001. Royalty income increased by \$24,000 (44%) to \$79,000 in 2001. Technology licensing income and sale of an option to technology were first recorded in 2001.

Aggregate sales of the two leading revenue generating products, First Defense® and the Kamar® Heatmount® Detector, totaled approximately \$5,692,000 (89% of total product sales) for the year ended December 31, 2001 as compared to approximately \$4,742,000 (86% of total product sales) for the year ended December 31, 2000. Aggregate sales of the three leading revenue generating products, First Defense, the Kamar Heatmount Detector and Wipe Out® Dairy Wipes totaled approximately \$6,095,000 (95% of total product sales) for the year ended December 31, 2001 as compared to approximately \$5,194,000 (95% of total product sales) for the year ended December 31, 2000. In 2001, for the first time, annual sales of First Defense exceeded annual sales of the Kamar Heatmount Detector. Sales of First Defense have benefited from the withdrawal of a competitive product from the market and from a significant increase in the value of calves. The sales of First Defense are seasonal with highest sales expected in the winter months. A sudden increase in sales volume resulted in an unexpected reduction in product inventory levels creating a backlog of orders worth approximately \$250,000 as of March 31, 2000. The backlog of orders was filled as of June 30, 2000 and then increased to approximately \$750,000 as of December 31, 2000. There was no backlog of orders as of December 31, 2001. Sales of the Kamar Heatmount Detector are subject to a license and distribution agreement that expires on December 31, 2004. Sales of Wipe Out were first recorded in 2000 following the December 1999 acquisition of the product.



Grant income increased to approximately \$133,000 (2% of total revenues) in 2001 as compared to \$96,000 (2% of total revenues) in 2000. Most of the grant income in 2001 supported work on the development of Mast Out™ and new approaches to the diagnosis of Johne's disease. In October 1997, the Company was awarded approximately \$710,000 under a federal research grant to partially fund the Company's efforts to develop a product to prevent Travelers' Diarrhea. In 1998, the remaining funding then available under this grant was reallocated to the development of DiffGAM. Approximately \$66,000 in grant income was recognized under this grant in 2000.

Product costs amounted to 50% of product sales in 2001 as compared to 51% in 2000. Internally developed products tend to have higher gross margin percentages than licensed-in products. Some deterioration of the gross margin percentage is anticipated as new products initially are developed and acquired. Over time, as these products are fully integrated into the Company's manufacturing and marketing operations, the Company expects to be able to improve the gross margin percentage. This is the case, for example, with Wipe Out® Dairy Wipes, a product that was acquired by the Company in December 1999. In 2001, the Company invested in the necessary facility addition and production equipment to eliminate the need for a subcontractor and be able to manufacture this product internally, which, the Company believes, should improve the gross margin. At this stage in the Company's development, management is focusing on growing the absolute dollar value of the gross margin on product sales. The gross margin on product sales earned in 2001 increased by \$497,000 (19%) to \$3,180,000 as compared to the gross margin earned in 2000.

The Company decreased its expenditures for research and development by approximately \$73,000 (8%) to \$849,000 in 2001 as compared to \$922,000 in 2000. Research and development expenses aggregated 13% and 16% of total revenues in 2001 and 2000, respectively. Research and development expenses exceeded grant and technology licensing income by approximately \$671,000 in 2001 and by \$826,000 in 2000. These "net" research and development expenses decreased to 10% of product sales in 2001 from 15% of product sales in 2000. During 1998, the Company shifted the primary focus of its research and development efforts to products for the animal health industry. To expand its commercialized line of products for use by dairy and beef producers, the Company has invested in the development of new diagnostic products leveraging the Company's experience with infectious diseases. The Company has also initiated development programs for certain disease preventive products. Before funding of DiffGAM development was stopped in 2000, the Company demonstrated preliminary efficacy in a phase I/II clinical trial to prevent and treat *Clostridium difficile*-associated diarrhea. For clinical development to proceed into more expensive Phase II and III trials, a partner would be required.

Sales and marketing expenses increased by approximately \$356,000 (35%) to \$1,359,000 in 2001, aggregating 21% of product sales in 2001, compared to 18% in 2000. The Company anticipated the modest increase in the ratio of these expenses to product sales as the Company initiated sales of new products in 2001. The Company continues to leverage its small sales force through veterinary distribution channels. General and administrative expenses increased by approximately \$87,000 (18%) to \$583,000 in 2001 as compared to \$496,000 in 2000. While the Company continues its efforts to control its general and administrative expenses while incurring all the necessary expenses associated with being a publicly held company, the increase is in proportion to the growth of the Company.

Interest and other income exceeded interest expense by approximately \$63,000 and \$26,000 in 2000 and 2001, respectively. Interest expense was incurred in both years on the Company's outstanding bank debt.

The income before taxes of \$697,000 for the year ended December 31, 2001 compares to \$476,000 for the year ended December 31, 2000. In 2001, the Company recorded tax expense at a relatively typical corporate effective tax rate resulting in net income of \$420,000 for the year ended December 31, 2001. During 1999, the taxable income was fully offset by available net operating loss carryforwards resulting in no tax expense being recorded. Given the two consecutive years of profitable results in 1999 and 2000 and the expectation of continued profitability, the Company recorded approximately \$1,746,000 in non-cash tax benefits in 2000 relating to the partial release of valuation allowances previously established against deferred tax benefits associated with certain net operating loss carryforwards that would offset future tax liabilities, in accordance with Financial Accounting Standards Board Statement No. 109. As a result of this accounting for income taxes, the Company recorded net income of \$2,222,000 for the year ended December 31, 2000.

#### *Fiscal 2000 Compared to Fiscal 1999*

Total revenues for the year ended December 31, 2000 of \$5,636,000 increased by \$727,000 (15%) from \$4,909,000 in 1999. Product sales for the year ended December 31, 2000 of \$5,485,000 were \$763,000 (16%) more than the product sales recorded in 1999. Sales of Wipe Out Dairy Wipes were first recorded in 2000. Product selling

prices have generally increased in line with inflation. Grant income decreased by \$91,000 (48%) to \$96,000 in 2000. Royalty income was first recorded in 2000.

Aggregate sales of First Defense® and the Kamar® Heatmount® Detector totaled approximately \$4,742,000 (86% of total product sales) for the year ended December 31, 2000 as compared to approximately \$4,517,000 (96% of total product sales) for the year ended December 31, 1999. The sales of First Defense are seasonal with highest sales expected in the winter months. Sales of First Defense increased by 25% in the fourth quarter of 1999 as compared to the fourth quarter of 1998 and increased by 10% during the year ended December 31, 2000 as compared to 1999. While these significant increases in sales are positive indications for the product in the long term, the resulting unexpected reduction in product inventory levels caused by the sudden increase in sales volume created a backlog of orders worth approximately \$250,000 as of March 31, 2000 that increased to approximately \$750,000 as of December 31, 2000.

Grant income decreased to approximately \$96,000 (2% of total revenues) in 2000 as compared to \$187,000 (4% of total revenues) in 1999. In October 1997, the Company was awarded approximately \$710,000 under a two-year federal research grant to partially fund the Company's efforts to develop a product to prevent Travelers' Diarrhea. In 1998, the remaining funding then available under this grant was reallocated to the development of DiffGAM. During 1999, the term of this grant was extended by one year to September 2000. Approximately \$66,000 and \$162,000 in grant income was recognized under this grant in 2000 and 1999, respectively. Grant income in 1999 also included approximately \$25,000 from the State of Maine partially funding early stage research of a bovine vaccine technology.

Product costs amounted to 51% of product sales in 2000 as compared to 46% in 1999. Internally developed products tend to have higher gross margin percentages than licensed-in products. Some deterioration of the gross margin percentage is anticipated as new products are developed and acquired. Over time, as these products are fully integrated into the Company's manufacturing and marketing operations, the Company expects to be able to improve the gross margin percentage. This is the case, for example, with Wipe Out® Dairy Wipes, a new product that was acquired by the Company in December 1999. The Company is investing in the necessary facility addition and production equipment to eliminate the need for a subcontractor and be able to manufacture this product internally, which, the Company believes, should improve the gross margin. At this stage in the Company's development, management is focusing on growing the absolute dollar value of the gross margin on product sales. The gross margin on product sales earned in 2000 increased by \$114,000 (4%) to \$2,684,000 as compared to the gross margin earned in 1999.

The Company increased its expenditures for research and development to approximately \$922,000 in 2000 as compared to \$813,000 in 1999. Research and development expenses aggregated 16% and 17% of total revenues in 2000 and 1999, respectively. Research and development expenses exceeded grant income by approximately \$826,000 in 2000 and by \$626,000 in 1999. These "net" research and development expenses increased to 15% of product sales in 2000 from 13% of product sales in 1999. During 1998, the Company shifted the primary focus of its research and development efforts to products for the animal health industry. To expand its commercialized line of products for use by dairy and beef producers, the Company has invested in the development of new diagnostic products leveraging the Company's experience with infectious diseases. The Company has also initiated early stage development programs of certain disease preventive products. The Company has demonstrated preliminary efficacy of DiffGAM in a phase I/II clinical trial to prevent and treat *Clostridium difficile*-associated diarrhea. However, for clinical development to proceed into more expensive Phase II and III trials, a partner would be required. The Company has also invested in the development of a test used to detect the presence of *Cryptosporidium parvum* in drinking water.

Sales and marketing expenses increased by approximately \$113,000 (13%) to \$1,003,000 in 2000, aggregating 18% of product sales in 2000, compared to 19% in 1999. The 13% increase in sales and marketing expenses in 2000 is consistent with the 16% increase in product sales. The Company anticipates the ratio of these expenses to product sales to increase modestly as the Company initiates sales of new products in 2001. The Company continues to leverage its small sales force through wholesale distribution channels. General and administrative expenses were approximately \$496,000 in 2000 as compared to \$439,000 in 1999. The Company has continued its efforts to control its general and administrative expenses while incurring all the necessary expenses associated with being a publicly held company.

Interest income exceeded interest expense by approximately \$63,000 and \$33,000 in 2000 and 1999, respectively. Interest expense was incurred in both years on the Company's outstanding bank debt. The Company's share of the loss in the equity of its joint venture (AgriCell Company, LLC) aggregated \$97,000 in 1999. No such expense was incurred in 2000. The Company's joint venture loss was principally caused by the limited sales of lactoferrin. The primary markets for this product at this time are in Asia, and sales have been negatively impacted by reduced demand from Asian customers and by a decrease in the world price for the commodity. As of December 31, 1999, the investment in this joint venture asset was completely written off. While the operations of the joint venture are

ongoing, any further losses incurred by the joint venture will have no impact on the Company's financial statements. Such losses could be carried forward to reduce any future taxable income distributed to the Company by the joint venture.

The income before taxes of \$476,000 for the year ended December 31, 2000 compares to \$551,000 for the year ended December 31, 1999. During 1999, the taxable income was fully offset by available net operating loss carryforwards resulting in no tax expenses being recorded. Given the two consecutive years of profitable results and the expectation of continued profitability, the Company recorded approximately \$1,746,000 in non-cash tax benefits relating to the partial release of valuation allowances previously established against deferred tax benefits associated with certain net operating loss carryforwards that would offset future tax liabilities, in accordance with Financial Accounting Standards Board Statement No. 109. As a result of this accounting for income taxes, the Company recorded net income of \$2,222,000 for the year ended December 31, 2000 compared to \$551,000 for the year ended December 31, 1999. Going forward, the Company expects to record tax expense at a relatively typical corporate effective tax rate.

#### *Financial Position, Liquidity and Capital Resources*

The Company's total assets increased to \$7,117,000 at December 31, 2001 from \$6,444,000 at December 31, 2000. The Company's cash balance as of December 31, 2001 decreased to \$1,883,000 from \$1,895,000 at December 31, 2000. Net working capital increased to \$2,943,000 at December 31, 2001 from \$2,894,000 at December 31, 2000. Stockholders' equity increased to \$6,046,000 at December 31, 2001 from \$5,539,000 at December 31, 2000.

During 2001, approximately \$906,000 in cash was provided by operating activities as the net income of \$420,000 was net of \$177,000 in non-cash depreciation and amortization expense. Additionally, tax expense includes approximately \$255,000 of non-cash items relating to deferred taxes. Approximately \$201,000 in cash was used to finance an increase in accounts receivable and inventories and to pay down current liabilities, and accrued expenses and deferred revenue increased by approximately \$255,000. Investing activities were comprised of an \$879,000 net investment in fixed assets and the \$85,000 acquisition of certain product rights. Financing activities were comprised of regular principal repayments on the Company's bank debt of approximately \$20,000 that were more than offset by the \$66,000 in proceeds from the issuance of common stock upon the exercise of stock options.

The Company funded its 2001 research and development expenses from government grants, technology licensing income and product sales. The Company's current profitability provides positive cash flow to fund all operating expenses as well as new product acquisitions while reporting a net operating income. During the year ended December 31, 2001, the \$3,180,000 gross margin from product sales more than funded the aggregate of \$2,613,000 in research and development expenses net of grant and technology licensing income ("net R&D") and selling, general and administrative ("S,G&A") expenses. In 2000, the \$2,684,000 gross margin more than funded the aggregate of \$2,325,000 in net R&D and S,G&A expenses. In 1999, the \$2,569,000 gross margin more than funded the aggregate of \$1,954,000 net R&D and S,G&A expenses. Since 1999, it has been the Company's strategy to focus its research and development efforts on animal health product opportunities, which are generally less expensive than human health product opportunities.

In March 2001, the Company received a two year grant award aggregating up to \$400,000 from the Maine Technology Institute, a non-profit corporation created by the General Assembly of the State of Maine. The grant augments the Company's development of its Nisin-based mastitis treatment, *Mast Out*<sup>TM</sup>, by funding significant portions of the costs related to conducting the clinical trials and developing the proprietary manufacturing process required to obtain FDA approval of the product. The grant award carries a contingent payback obligation of either the full amount of the paid award within two years of first commercial sale of a product developed with the funding or, at the Company's option, two times the full amount of the paid award, which could be paid as a 2% royalty on such product sales, if any. Because of this contingent payback obligation, the funding is being recorded as deferred revenue as the cash is received by the Company, and no income is being recognized to match the development expenses as they are incurred. There is no payback obligation in the event that a product is not commercialized. In such case, the deferred revenue would be recognized at the time the product development effort is discontinued. The Company received \$100,000 under this grant in 2001 and another \$50,000 in February 2002.

Since 1990, the Company has been awarded seven Phase I and three Phase II Small Business Innovation Research ("SBIR") grants from the National Institutes of Health. In addition, the Company has been awarded two Phase I SBIR grants from the USDA and three grants from the State of Maine and one grant from the American Water Works Research Foundation. These grants aggregate approximately \$3,013,000 in funding for the Company's research and development programs. In recognition of this successful grant award history, the Company was named the Tibbetts Award Winner for Maine in 2001 by the U.S. Small Business Administration. Approximately \$2,066,000 of this grant

income was recognized prior to 2001, approximately \$133,000 was recognized in 2001, and approximately \$415,000 is expected to be recognized after 2001 (not including the \$400,000 award from the Maine Technology Institute, described above). Approximately \$2,378,000 of this grant funding was awarded by the National Institutes of Health and \$455,000 by the State of Maine and \$140,000 by the USDA. In addition to the \$1,891,000 that supported the development of the Company's milk antibody products for humans, approximately \$666,000 has been awarded in support of the Mast Out™ development program, \$191,000 has been awarded in support of skin sanitizing applications of Nisin, \$140,000 was awarded in support of Crypto-Scan® and \$70,000 has been awarded in support of new approaches to the diagnosis of Johne's disease. The Company continues to seek research grant support as a means of leveraging the funds that it is able to spend developing new products.

Long-term bank debt decreased to \$392,000 at December 31, 2001, from \$414,000 at December 31, 2000. The current portion of this debt obligation increased to \$22,000 at December 31, 2001 from \$20,000 at December 31, 2000. The Company is obligated to make monthly principal and interest payments aggregating approximately \$5,000 under the outstanding debt obligation. (See Note 4 to the accompanying financial statements for further detail on these debt obligations).

In December 2000, the Company initiated a \$680,000 construction project to add a 5,300 square foot addition to its facility, which project was completed in May 2001. This additional manufacturing space was needed to increase production of First Defense® and to bring the manufacture of Wipe Out® Dairy Wipes in-house. To implement efficiencies in the manufacture of Wipe Out, the Company invested approximately \$225,000 of cash in the acquisition of equipment necessary to eliminate the need for a subcontractor and enable the Company to manufacture the product at its facility. The projects were paid for with approximately \$100,000 and \$800,000 of available cash in 2000 and 2001, respectively.

#### *Forward-Looking Statements*

The statements contained in this report which are not historical fact are "forward-looking statements" that involve various important assumptions, risks, uncertainties and other factors. There can be no assurance that actual results will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors including, but not limited to, the risk factors discussed below. The Company is heavily dependent on the successful development of new products for its future growth. These new products have the potential to increase the Company's profitability.

It is the Company's objective to fund all selling, general and administrative expenses as well as all research and development expenditures that are not funded by an outside source with the gross margin earned from product sales. Continuation of the Company's profitability in the near term will, in large part, be determined by the ongoing successful marketing of First Defense and the Kamar® Heatmount® Detector. Growth in the Company's profitability beyond the year 2004 will, in large part, be determined by the success of the Company's efforts to market its new products, as well as its ability to effectively develop and acquire additional animal health products. The Company needs to successfully develop and commercialize new products to replace the anticipated decrease in revenue to be caused by the December 31, 2004 expiration of the license to sell the Kamar Heatmount Detector.

To advance the development of Mast Out toward FDA licensure, the Company would be required to incur significant, non-recurring outside laboratory expenses to fund the required toxicology, safety and efficacy trials. The Company anticipates that these expenses could aggregate approximately \$500,000. Depending on the timing of when these expenses are incurred, the Company's continuing quarterly profitability could be jeopardized while management expects to be able to maintain its annual profitability objectives. These non-recurring outside laboratory expenses could cause the Company to temporarily deviate from its objective of keeping internally funded research and development expenses close to 13% of product sales. Given the potential sales that could be achieved for this product if it is successfully developed and approved by the FDA, management believes the significant investment is warranted. The Company estimates that North American sales of what could be the first non-antibiotic treatment for mastitis in lactating cows could approximate \$5,000,000. Management believes that a similar sales potential exists in markets outside of North America.

It is estimated that Johne's disease (caused by *Mycobacterium paratuberculosis*) costs the U.S. dairy industry \$100 to \$200 million per year. Sales of Tip-Test®: Johne's have been severely limited by state regulatory policies and by a resistance on the part of producers to want to know the status of their herds because of the burdens associated with known positive test results. The Company is working with regulatory authorities to facilitate more frequent Johne's testing as a way to help reduce the disease incidence rate.

The Company anticipates being able to earn a royalty of approximately \$100,000 per year from the use of its technology in the production of whey protein isolate by an Australian partner for as long as the applicable technology license arrangement remains in effect.

### *Risk Factors*

The development of these new products is subject to financial, efficacy, regulatory and market risks. There can be no assurance that the Company will be able to finance the development of these new product opportunities nor that, if financed, the new products will be found to be efficacious and gain the appropriate regulatory approval. Furthermore, if regulatory approval is obtained, there can be no assurance that the market estimates will prove to be accurate or that market acceptance at a profitable price level can be achieved or that the products can be profitably manufactured.

### *Effects of Inflation and Interest Rates*

The Company believes that neither inflation nor interest rates have had a significant effect on revenues and expenses.

### *Critical Accounting Policies*

The consolidated financial statements are presented on the basis of accounting principles that are generally accepted in the U.S. All professional accounting standards that are effective as of December 31, 2001 have been taken into consideration in preparing the consolidated financial statements. The preparation of consolidated financial statements requires that the Company make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, including those related to revenue recognition, investments, intangible and long lived assets, income taxes and contingencies. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The Company has chosen to highlight certain policies that it considers critical to the operations of the business and understanding its consolidated financial statements.

Revenues related to the sale of manufactured products are recorded at the time of shipment to the customer and when collectibility is reasonably assured. Non-refundable grant income is recognized as reimbursable expenses are incurred. Indirect costs which are billed to the government are subject to their review. All research and development costs are expensed as incurred, as are all patent costs. Royalty income is recorded on the accrual basis based on sales as reported to the Company by its licensee pursuant to the terms of the agreement.

Revenues from non-refundable upfront payments are deferred and recognized ratably over the period during which the earning process is completed. A grant award of up to \$400,000 carries a contingent payback obligation of either the full amount of the paid award within two years of first commercial sale of a product developed with the funding or, at the Company's option, two times the full amount of the paid award, which could be paid as a 2% royalty on such product sales, if any. Because of this contingent payback obligation, the funding is being recorded as deferred revenue as the cash is received by the Company, and no income is being recognized to match the development expenses as they are incurred. There is no payback obligation in the event that a product is not commercialized. In such case, the deferred revenue would be recognized at the time the product development effort is discontinued. Technology licensing income is being recognized over the twenty-two month period ending in December 2002, which represents the period during which the Company has agreed to provide clinical material to the licensee at a discount. Income from the sale of an option to technology is being recognized over the twenty month period ending in March 2003, which represents the period during which the option holder has the right to exercise its option to the related technology. Should the option holder exercise the option, the negotiated sales price for the technology is \$1,300,000, which amount would be recognized when the option is exercised. As of December 31, 2001, the Company had recorded approximately \$230,000 in deferred revenue comprised of \$100,000 relating to grant income, \$55,000 relating to technology licensing income and \$75,000 relating to the sale of an option to technology, described above.

Inventories include raw materials, work-in-process and finished goods and are recorded at the lower of standard cost which approximates cost on the first-in, first-out method or market (net realizable value). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead.

The Company utilized approximately \$866,000 and \$527,000 of net operating loss carryforwards to offset taxable income in fiscal years 2000 and 2001, respectively. As a result of the Company's two consecutive years of profitable results in 1999 and 2000 and the expectation of continued profitability, the Company recorded a tax benefit of approximately \$1,967,000 in fiscal 2000 as a result of the release of the valuation allowance on the deferred tax asset related to net operating loss carryforwards. The remaining valuation allowance of approximately \$154,000 and \$139,000, related to the general business credit carryforward as of December 31, 2000 and 2001, respectively, has not been released due to the uncertainty of its use before expiration. This credit expires in the years 2002 through 2006. For federal and state income tax purposes, the Company has remaining net operating loss carryforwards of approximately \$3,319,000, expiring from 2003 to 2018, that are available to offset future taxable income.

Accounts receivable are recorded net of a valuation allowance for doubtful accounts of approximately \$39,000 and \$38,000 at December 31, 2000 and 2001, respectively.

#### ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and financial statement schedule of the Company, together with the notes thereto and the report of the independent accountants thereon, are set forth on Pages F-1 through F-17 at the end of this report.

#### ITEM 9 - CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

#### PART III

#### ITEM 10 - DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

(A) Information with respect to the Company's directors is incorporated herein by reference to the section of the Company's 2002 Proxy Statement titled "Election of the Board of Directors", which is intended to be filed with the Securities and Exchange Commission within 120 days after the end of the Company's fiscal year.

(B) The Company's executive officers are as follows:

MICHAEL F. BRIGHAM (Age: 41, Officer Since: October 1991, Director Since: March 1999) was appointed to serve as President and Chief Executive Officer in February 2000, while maintaining the titles of Treasurer and Secretary, and was appointed to serve as a Director of the Company in March 1999. He previously had been elected Vice President of the Company in December 1998 and served as Chief Financial Officer since October 1991. He has served as Secretary since December 1995 and as Treasurer since October 1991. Prior to that, he served as Director of Finance and Administration since originally joining the Company in September 1989. Mr. Brigham serves on the Board of Directors of the Biotechnology Association of Maine and of the Maine Center for Innovation in Biotechnology. Prior to joining the Company, he was employed as an audit manager for the public accounting firm of Ernst & Young. Mr. Brigham earned his Masters in Business Administration from New York University in 1989.

JOSEPH H. CRABB, Ph.D. (Age: 47, Officer Since: March 1996, Director Since: March 2001) was appointed to serve as a Director of the Company in March 2001, having previously served in that capacity during the period from March 1999 until February 2000, and was elected Vice President of the Company in December 1998, while maintaining the title of Chief Scientific Officer. He has served as Chief Scientific Officer since September 1998. Prior to that, he served as Vice President of Research and Development since March 1996. Prior to that, he served as Director of Research and Development and Senior Scientist since originally joining the Company in November 1988. Dr. Crabb currently holds a Clinical Assistant Professorship at Tufts University School of Veterinary Medicine and serves on National Institutes of Health and American Water Works Association advisory committees. Prior to joining the Company in 1988, Dr. Crabb earned his Ph.D. in Biochemistry from Dartmouth Medical School and completed postdoctoral studies in microbial pathogenesis at Harvard Medical School, where he also served on the faculty.

There is no family relationship between any director, executive officer, or person nominated or chosen by the Company to become a director or executive officer.

## ITEM 11 - EXECUTIVE COMPENSATION

Information regarding cash compensation paid to executive officers of the Company is incorporated herein by reference to the section of the Company's 2002 Proxy Statement titled "Executive Compensation", which is intended to be filed with the Securities and Exchange Commission within 120 days after the end of the Company's fiscal year.

## ITEM 12 - SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Information regarding ownership of the Company's common stock by certain owners and management is incorporated herein by reference to the section of the Company's 2002 Proxy Statement titled "Security Ownership of Certain Beneficial Owners and Management", which is intended to be filed with the Securities and Exchange Commission within 120 days after the end of the Company's fiscal year.

## ITEM 13 - CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Information regarding certain relationships and related transactions is incorporated herein by reference to the section of the Company's 2002 Proxy Statement titled "Certain Relationships and Related Transactions", which is intended to be filed with the Securities and Exchange Commission within 120 days after the end of the Company's fiscal year.

## PART IV

## ITEM 14 - EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

### *(a) Exhibits*

- 3.1 Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's 1987 Registration Statement Number 33-12722 on Form S-1 as filed with the Commission).
- 3.2 Certificate of Amendment to the Company's Certificate of Incorporation (incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended June 30, 1990).
- 3.3 Certificate of Amendment to the Company's Certificate of Incorporation effective August 24, 1992 (incorporated by reference to Exhibit 3.4 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1992).
- 3.4 Bylaws of the Registrant as amended (incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995).
- 4.1 Rights Agreement dated as of September 5, 1995, between the Registrant and American Stock Transfer and Trust Co., as Rights Agent, which includes as Exhibit A thereto the form of Right Certificate and as Exhibit B thereto the Summary of Rights to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated September 5, 1995).
- 4.2 \$480,000 Note Payable to Peoples Heritage Bank dated May 6, 1998 (incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q for the three months ended June 30, 1998).
- 4.3 Common Stock Purchase Warrant issued by the Registrant to Nutrition 21, Inc. dated April 12, 2000 (incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended June 30, 2000).
- 10.1+ 1989 Stock Option and Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1989).
- 10.2+ Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1989).
- 10.3+ Form of Indemnification Agreement entered into with each of the Company's directors and officers (incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1989).
- 10.4+ Amendment, dated April 1992, to Employment Agreement dated November 1991, between the Registrant and Michael F. Brigham (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1992).
- 10.5+ Amendment, dated April 1992, to Employment Agreement dated November 1991, between the Registrant and Joseph H. Crabb (incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995).

- 10.6 License and Supply Agreement between Bio-Vac, Inc. and the Registrant dated June 15, 1993 (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993).
- 10.7 Distribution and Licensing Agreement between Kamar, Inc. and the Registrant dated December 3, 1993 (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993).
- 10.8(1) Exclusive License Agreement between The Regents of the University of California of Alameda, California and the Registrant dated February 23, 1994 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the three months ended March 31, 1994).
- 10.9+ 1995 Stock Option Plan for Outside Directors (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the three months ended June 30, 1995).
- 10.10+ Form of Stock Option Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the three months ended June 30, 1995).
- 10.11 Limited Liability Company Agreement of AgriCell Company, LLC dated as of September 10, 1996 between the Registrant and Agri-Mark, Inc. of Methuen, MA (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the three months ended September 30, 1996).
- 10.12(2) License Agreement between the Registrant and Murray Goulburn Co-operative Co., Limited, dated November 14, 1997 (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997).
- 10.13(3) Amendment No. 1 to Distribution and Licensing Agreement between the Registrant and Kamar, Inc. dated July 1, 1998 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the three months ended September 30, 1998).
- 10.14+ Employment Agreement dated April 29, 1999 between the Registrant and Michael F. Brigham (incorporated by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999).
- 10.15+ Employment Agreement dated April 29, 1999 between the Registrant and Joseph H. Crabb (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999).
- 10.16 Asset Purchase Agreement between the Registrant and Nutrition 21, Inc. dated December 30, 1999 (incorporated by reference to Exhibit 2 to the Registrant's Current Report on Form 8-K dated as of December 30, 1999).
- 10.17+ 2000 Stock Option and Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended June 30, 2000).
- 10.18+ Form of Incentive Stock Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended June 30, 2000).
- 10.19+ 2000 Stock Option Plan for Outside Directors of the Registrant (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended June 30, 2000).
- 10.20+ Form of Stock Option Agreement (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended June 30, 2000).
- 10.21(4) Amendment No. 2 to Distribution and Licensing Agreement between the Registrant and Kamar, Inc. dated September 28, 2000 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended September 30, 2000).
- 21.1 Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1996).
- 23.1 Consent of PricewaterhouseCoopers LLP.

(1) Confidential Treatment as to certain portions obtained effective until March 31, 2002. The copy filed as an exhibit omits the information subject to the Confidential Treatment.

(2) Confidential Treatment as to certain portions obtained effective until November 14, 2012. The copy filed as an exhibit omits the information subject to the Confidential Treatment.

(3) Confidential Treatment as to certain portions obtained effective until December 31, 2003. The copy filed as an exhibit omits the information subject to the Confidential Treatment.

(4) Confidential Treatment as to certain portions has been requested effective until December 31, 2004. The copy filed as an exhibit omits the information subject to the confidentiality request.

+ Management contract or compensatory plan or arrangement.



*(b) Index to Financial Statements*

Report of PricewaterhouseCoopers LLP, Independent Accountants	F-1
Consolidated Balance Sheets - December 31, 2000 and 2001	F-2 to F-3
Consolidated Statements of Operations for the years ended December 31, 1999, 2000 and 2001	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 1999, 2000 and 2001	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 1999, 2000 and 2001	F-6
Notes to Consolidated Financial Statements	F-7 to F-16

<i>(c) Schedule 2-Supplemental Valuation and Qualifying Accounts</i>	F-17
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*(d) Reports on Form 8-K*

None

PricewaterhouseCoopers LLP  
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Facsimile (207) 774 1297

REPORT OF INDEPENDENT ACCOUNTANTS

Board of Directors and Shareholders of  
ImmuCell Corporation:

In our opinion, the consolidated financial statements listed in the index appearing under Item 14(b) of this Form 10-K present fairly, in all material respects, the financial position of ImmuCell Corporation and Subsidiary at December 31, 2000 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 14(c) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and the financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and the financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

*PricewaterhouseCoopers LLP*

Portland, Maine  
January 25, 2002

# IMMUCELL CORPORATION AND SUBSIDIARY

## CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2000 and 2001

ASSETS		
	2000	2001
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$1,895,149	\$1,883,090
Accounts receivable, net of allowance for doubtful accounts of \$39,000 and \$38,000 at December 31, 2000 and 2001, respectively	875,066	974,383
Inventories	502,448	533,864
Current portion of deferred tax asset	77,651	78,650
Prepaid expenses	34,680	37,103
Total current assets	3,384,994	3,507,090
<b>PROPERTY, PLANT AND EQUIPMENT, at cost:</b>		
Laboratory and manufacturing equipment	1,005,914	1,326,111
Building and improvements	586,242	1,270,551
Construction in progress	219,269	--
Office furniture and equipment	73,347	105,116
Land	50,000	50,000
	1,934,772	2,751,778
Less-accumulated depreciation	988,374	1,067,538
Net property, plant and equipment	946,398	1,684,240
<b>DEFERRED TAX ASSET</b>	1,851,684	1,616,416
<b>PRODUCT RIGHTS AND OTHER ASSETS, net of amortization of \$25,000 and \$61,000 at December 31, 2000 and 2001, respectively</b>	260,840	309,471
<b>TOTAL ASSETS</b>	<b>\$6,443,916</b>	<b>\$7,117,217</b>

=====

The accompanying notes are an integral part of these financial statements.

# IMMUCELL CORPORATION AND SUBSIDIARY

## CONSOLIDATED BALANCE SHEETS DECEMBER 31, 2000 and 2001

### LIABILITIES AND STOCKHOLDERS' EQUITY

	2000	2001
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 239,254	\$ 171,260
Accrued expenses	226,010	256,575
Current portion of long term debt	20,481	22,317
Deferred revenue	5,000	114,280
<b>Total current liabilities</b>	<b>490,745</b>	<b>564,432</b>
<b>LONG TERM LIABILITIES:</b>		
Long term debt	414,178	391,861
Long term portion of deferred revenue	--	115,270
<b>Total long term liabilities</b>	<b>414,178</b>	<b>507,131</b>
<b>COMMITMENTS AND CONTINGENT LIABILITIES (NOTE 7)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock, Par value - \$.10 per share		
Authorized-8,000,000 shares		
Issued-3,054,782 and 3,115,082		
shares at December 31, 2000 and		
2001, respectively	305,478	311,508
Capital in excess of par value	8,833,785	8,913,981
Accumulated deficit	(3,013,535)	(2,593,100)
Treasury stock, at cost-389,598 shares	(586,735)	(586,735)
<b>Total stockholders' equity</b>	<b>5,538,993</b>	<b>6,045,654</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$6,443,916</b>	<b>\$7,117,217</b>
	=====	=====

The accompanying notes are an integral part of these financial statements.

**IMMUCELL CORPORATION AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF OPERATIONS  
FOR THE YEARS ENDED DECEMBER 31,**

	1999	2000	2001
<b>REVENUES:</b>			
Product sales	\$4,722,374	\$5,485,003	\$6,395,140
Grant income	186,871	96,266	132,581
Royalty income	--	54,716	78,595
Technology licensing income	--	--	45,450
Sale of option to technology	--	--	25,000
<b>Total revenues</b>	<b>4,909,245</b>	<b>5,635,985</b>	<b>6,676,766</b>
<b>COSTS AND EXPENSES:</b>			
Product costs	2,152,959	2,801,392	3,214,984
Research and development expenses	812,892	922,347	849,174
Sales and marketing expenses	889,501	1,002,910	1,358,563
General and administrative expenses	438,923	495,962	583,161
<b>Total costs and expenses</b>	<b>4,294,275</b>	<b>5,222,611</b>	<b>6,005,882</b>
Net operating income	614,970	413,374	670,884
Interest and other income	72,763	100,816	62,671
Interest expense	(39,757)	(38,302)	(36,515)
Equity in net loss of joint venture	(97,133)	--	--
<b>Net interest and other</b>	<b>(64,127)</b>	<b>62,514</b>	<b>26,156</b>
<b>INCOME BEFORE TAXES</b>	<b>550,843</b>	<b>475,888</b>	<b>697,040</b>
<b>TAX BENEFIT (EXPENSE)</b>	<b>--</b>	<b>1,746,158</b>	<b>(276,605)</b>
<b>NET INCOME</b>	<b>\$ 550,843</b>	<b>\$2,222,046</b>	<b>\$ 420,435</b>
=====			
<b>NET INCOME PER COMMON SHARE:</b>			
Basic	\$ 0.23	\$ 0.84	\$ 0.15
Diluted	\$ 0.22	\$ 0.79	\$ 0.15
=====			
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:</b>			
Basic	2,432,701	2,632,038	2,717,857
Diluted	2,519,962	2,822,964	2,836,309
=====			

The accompanying notes are an integral part of these financial statements.

IMMUCELL CORPORATION AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
FOR THE YEARS ENDED DECEMBER 31, 1999, 2000 and 2001

	Common Stock		Capital in		Accumulated	Treasury Stock		Total
	\$.10 Par Value		Excess of	Par Value		Shares	Amount	
	Shares	Amount			Deficit			Stockholders' Equity
BALANCE, December 31, 1998	2,818,482	\$281,848	\$8,338,907	\$(5,786,424)		389,598	\$(586,735)	\$2,247,596
Net income	--	--	--		550,843	--	--	550,843
Exercise of stock options	16,200	1,620	15,339	--	--	--	--	16,959
BALANCE, December 31, 1999	2,834,682	283,468	8,354,246	(5,235,581)		389,598	(586,735)	2,815,398
Net income	--	--	--	2,222,046		--	--	2,222,046
Tax benefits related to stock options	--	--	183,177	--	--	--	--	183,177
Exercise of stock options	220,100	22,010	296,362	--	--	--	--	318,372
BALANCE, December 31, 2000	3,054,782	305,478	8,833,785	(3,013,535)		389,598	(586,735)	5,538,993
Net income	--	--	--	420,435		--	--	420,435
Tax benefits related to stock options	--	--	20,363	--	--	--	--	20,363
Exercise of stock options	60,300	6,030	59,833	--	--	--	--	65,863
BALANCE, December 31, 2001	3,115,082	\$311,508	\$8,913,981	\$(2,593,100)		389,598	\$(586,735)	\$6,045,654

The accompanying notes are an integral part of these financial statements.

# IMMUCELL CORPORATION AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED DECEMBER 31,

	1999	2000	2001
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income	\$ 550,843	\$2,222,046	\$ 420,435
Adjustments to reconcile net income to net cash provided by operating activities-			
Depreciation and amortization	101,537	133,158	176,725
Deferred income taxes	--	(1,746,158)	254,632
Equity share in joint venture losses	97,134	--	--
Changes in:			
Accounts receivable	(203,385)	(421,927)	(99,317)
Inventories	(44,707)	18,208	(31,416)
Prepaid expenses	17,690	(6,854)	(2,423)
Accounts payable	181,929	(82,987)	(67,994)
Accrued expenses	(26,342)	(33,981)	30,565
Deferred revenue	5,000	--	224,550
Net cash provided by operating activities	679,699	81,505	905,757
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property, plant and equipment	(131,595)	(274,726)	(895,504)
Loss on disposal of fixed assets	--	--	16,890
Investment in joint venture	(13,023)	--	--
Acquisition of product rights	(250,000)	(35,000)	(84,584)
Net cash used for investing activities	(394,618)	(309,726)	(963,198)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Payments of debt obligations	(17,257)	(18,690)	(20,481)
Proceeds from exercise of stock options	16,959	318,372	65,863
Net cash (used for) provided by financing activities	(298)	299,682	45,382
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	284,783	71,461	(12,059)
<b>BEGINNING CASH AND CASH EQUIVALENTS</b>	1,538,905	1,823,688	1,895,149
<b>ENDING CASH AND CASH EQUIVALENTS</b>	\$1,823,688	\$1,895,149	\$1,883,090
<b>CASH PAID FOR INTEREST</b>	\$ 39,883	\$ 38,438	\$ 36,664

The accompanying notes are an integral part of these financial statements.

# IMMUCELL CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### (1) BUSINESS OPERATIONS

ImmuCell Corporation (the "Company") is a biotechnology company primarily engaged in the marketing and development of animal health products to expand its commercialized line of products for use by dairy and beef producers. The Company was originally incorporated in Maine in 1982 and reincorporated in Delaware in March 1987, in conjunction with its initial public offering of common stock.

The Company is subject to certain risks associated with its stage of development including dependence on key individuals, competition from other larger companies, the successful marketing of existing products and the development and acquisition of additional commercially viable products with appropriate regulatory approvals, where applicable. In addition, sales of a significant product are subject to a license that is scheduled to expire on December 31, 2004.

### (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### (a) Consolidation Principles

The consolidated financial statements of the Company include the accounts of the Company and its wholly-owned subsidiary, the Kamar Marketing Group, Inc. All intercompany accounts and transactions have been eliminated in consolidation.

#### (b) Cash and Cash Equivalents

The Company considers all highly liquid investment instruments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents are principally invested in U.S. government money market accounts and treasury bills.

#### (c) Inventories

Inventories include raw materials, work-in-process and finished goods and are recorded at the lower of standard cost which approximates cost on the first-in, first-out method or market (net realizable value). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead.

Inventories consist of the following:

	<u>December 31,</u>	
	<u>2000</u>	<u>2001</u>
Raw materials	\$110,728	\$223,826
Work-in-process	336,087	245,943
Finished goods	55,633	64,095
	<u>\$502,448</u>	<u>\$533,864</u>
	=====	=====

#### (d) Equipment, Building and Improvements

The Company provides for depreciation on the straight-line method by charges to operations in amounts estimated to allocate the cost of the assets from the date they are first put into use to the end of the estimated useful lives of the assets. The cost of the building and the addition thereto is being depreciated over the thirty year period ending in 2023, and related building improvements are depreciated over ten year periods. Fixed assets are depreciated over their useful lives that are generally estimated to be from three to ten years.



**(e) Intangible Assets**

The Company provides amortization on the straight-line method by charges to operations in amounts estimated to allocate the cost of the assets from the date they are first put into use to the end of the estimated useful lives of the assets. The \$250,000 acquisition of certain product rights in December 1999 is being amortized to cost of sales over the ten year period ending in December 2009, and the related manufacturing rights acquired in May 2001 for \$45,000 are being amortized over the balance of the period remaining through December 2009. The \$75,000 acquisition of certain other product rights that was paid for in two installments in December 2000 and July 2001 is valued at cost and is being amortized to cost of sales over the periods ending in June 2008. Intangible assets are tested annually for impairment or on an interim basis if indications of possible impairment arise. No material changes are anticipated in the remaining useful lives of intangible assets.

**(f) Revenue Recognition**

Revenues related to the sale of manufactured products are recorded at the time of shipment to the customer and when collectibility is reasonably assured. Non-refundable grant income is recognized as reimbursable expenses are incurred. Indirect costs which are billed to the government are subject to their review. All research and development costs are expensed as incurred, as are all patent costs. Royalty income is recorded on the accrual basis based on sales as reported to the Company by its licensee pursuant to the terms of the agreement.

Revenues from non-refundable upfront payments are deferred and recognized ratably over the period during which the earning process is completed. A grant awarded to the Company in 2001 for up to \$400,000 carries a contingent payback obligation of either the full amount of the paid award within two years of first commercial sale of a product developed with the funding or, at the Company's option, two times the full amount of the paid award, which could be paid as a 2% royalty on such product sales, if any. Because of this contingent payback obligation, the funding is being recorded as deferred revenue as the cash is received by the Company, and no income is being recognized to match the development expenses as they are incurred. There is no payback obligation in the event that a product is not commercialized. In such case, the deferred revenue would be recognized at the time the product development effort is discontinued. Technology licensing income is being recognized over the twenty-two month period ending in December 2002, which represents the period during which the Company has agreed to provide clinical material to the licensee at a discount. Income from the sale of an option to technology is being recognized over the twenty month period ending in March 2003, which represents the period during which the option holder has the right to exercise its option to the related technology. Should the option holder exercise the option, the negotiated sales price for the technology is \$1,300,000, which amount would be recognized when the option is exercised. As of December 31, 2001, the Company had recorded approximately \$230,000 in deferred revenue comprised of \$100,000 relating to grant income, \$55,000 relating to technology licensing income and \$75,000 relating to the sale of an option to technology, described above.

**(g) Net Income Per Common Share**

The basic net income per common share has been computed in accordance with Financial Accounting Standards Board Statement No. 128 by dividing the net income by the weighted average number of common shares outstanding during the year. The denominator in the diluted net income per common share calculation in 1999 was increased by 409,800 "in-the-money" common stock options and reduced by 322,539 shares that could have been repurchased with the proceeds from the exercise of these common stock options. Options to purchase 168,667 shares of common stock at prices ranging from \$1.69 to \$4.00 per share were outstanding during 1999 but not included in the computation of diluted net income per share because the options' exercise prices were greater than the average market price of the common shares and, therefore, the effect would be antidilutive. The denominator in the diluted net income per common share calculation in 2000 was increased by 597,738 "in-the-money" common stock options and reduced by 406,812 shares that could have been repurchased with the proceeds from the exercise of these common stock options. Options to purchase 24,000 shares of common stock at \$4.00 per share were outstanding during 2000 but not included in the computation of diluted net income per share because the options' exercise prices were greater than the average market price of the common shares and, therefore, the effect would be antidilutive. The denominator in the diluted net income per common share calculation in 2001 was increased by 350,938 "in-the-money" common stock options and reduced by 232,486 shares that could have been repurchased with the proceeds from the exercise of these common stock options. Options to purchase 330,000 shares of common stock at prices ranging from \$2.93 to \$4.00 per share were outstanding during 2001 but not included in the computation of diluted net income per share, because the options' exercise prices were greater than the average market price of the common shares and, therefore, the effect would be antidilutive. For additional disclosures regarding the outstanding common stock options see Note 6(b) and (c).

(h) Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual amounts could differ from those estimates.

(i) Segment Information

The Company discloses segment information in accordance with Statement of Financial Accounting Standards ("SFAS") No. 131, *Disclosures about Segments of an Enterprise and Related Information*. SFAS No. 131 designates the internal organization that is used by management for making operating decisions and assessing performance as the source of the Company's reportable segments. SFAS No. 131 also requires disclosures about products and services, geographic areas, and major customers.

(j) New Accounting Pronouncements

For all business combinations subsequent to June 30, 2001, the Company is required to apply the provisions of SFAS No. 141, "Business Combinations." SFAS 141 requires the use of the purchase method of accounting for all business combinations. Goodwill will initially be recognized as an asset and measured as the excess of the costs of the acquired entity over the net amounts assigned to the assets acquired and liabilities assumed. Intangible assets other than goodwill will be recognized as an asset apart from goodwill if that asset arises from contractual or legal rights. This pronouncement had no effect on the financial statements.

SFAS No. 142, "Goodwill and Other Intangible Assets," was issued in July 2001 and addresses financial accounting and reporting for acquired goodwill and other intangible assets. Under the provisions of SFAS No. 142, there will be no amortization of goodwill or intangible assets with indefinite lives. Impairment of these assets will need to be assessed annually and in the event an event occurs which indicates that goodwill may be impaired. The provisions of SFAS No. 142 are required to be applied starting with fiscal years beginning after December 15, 2001, and must be applied at the beginning of a fiscal year and to all goodwill and other intangible assets recognized in the financial statements at that date. The Company will adopt the provisions of this statement on January 1, 2002. The Company has determined that this pronouncement will not have a material effect on the financial statements.

SFAS No. 143, "Accounting for Asset Retirement Obligations," was issued in August 2001 and establishes financial accounting and reporting standards for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. The provisions of SFAS No. 143 apply to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and/or the normal operation of a long-lived asset, except for certain obligations of lessees. The Company will adopt the provisions of this statement on January 1, 2002. The Company has determined that this pronouncement will not have a material effect on the financial statements.

SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," was issued in October 2001. SFAS No. 144 provides new guidance on the recognition of impairment losses on long-lived assets to be held and used or to be disposed of and also broadens the definition of what constitutes a discontinued operation and how the results of a discontinued operation are to be measured and presented. The Company will adopt the provisions of this statement on January 1, 2002. The Company has determined that this pronouncement will not have a material effect on the financial statements.

(3) ACCRUED EXPENSES

Accrued expenses consisted of the following:

	<u>December 31,</u>	
	<u>2000</u>	<u>2001</u>
Accrued royalties	\$ 91,730	\$ 56,450
Accrued professional fees	25,875	36,977
Accrued payroll	41,327	88,188
Accrued other	67,078	74,960
	<u>\$226,010</u>	<u>\$256,575</u>
	=====	=====

(4) DEBT OBLIGATIONS

The Company has long term debt obligations, net of current maturities, as follows:

	<u>December 31,</u>	
	<u>2000</u>	<u>2001</u>
8.62% Bank mortgage, collateralized by first security interest in building, due 2001 to 2003	\$434,659	\$414,178
Less current portion	<u>20,481</u>	<u>22,317</u>
Long term debt	<u>\$414,178</u>	<u>\$391,861</u>
	=====	=====

The Company's building mortgage has a 15 year amortization schedule with interest payable at the fixed rate of 8.62% per year for the first five years. The Company intends to repay the then outstanding principal in May 2003, but the mortgage does provide the option of resetting at a new fixed interest rate to be determined at that time for one additional five year period. Principal payments under the above debt obligations due subsequent to December 31, 2001 are approximately as follows: \$22,000 in 2002 and \$392,000 in 2003. The difference between the fair value and the carrying value of these debt obligations is immaterial.

(5) INCOME TAXES

The Company accounts for income taxes in accordance with Financial Accounting Standards Board Statement No. 109. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The significant components of the Company's deferred tax assets and liabilities are as follows:

	<u>December 31,</u>	
	<u>2000</u>	<u>2001</u>
Deferred tax assets:		
Net operating loss carryforward	\$1,523,424	\$1,323,962
Expenses currently deductible	77,651	78,650
Depreciation	0	5,265
Research and experimentation amortization	331,163	287,189
General business credit carryforward	<u>153,968</u>	<u>139,233</u>
Total deferred tax assets	<u>2,086,206</u>	<u>1,834,299</u>
Deferred tax liabilities:		
Depreciation	<u>(2,903)</u>	<u>--</u>
Total deferred tax liabilities	<u>(2,903)</u>	<u>--</u>
Net deferred tax assets		
before valuation allowance	2,083,303	1,834,299
Valuation allowance	<u>(153,968)</u>	<u>(139,233)</u>
Net deferred tax assets	<u>\$1,929,335</u>	<u>\$1,695,066</u>

The income tax (benefit) provision consists of the following as of December 31<sup>st</sup> of the following years:

	<u>1999</u>	<u>2000</u>	<u>2001</u>
Current			
Federal	--	142,174	15,805
State	--	41,003	18,671
Foreign	--	--	<u>7,860</u>
	--	<u>183,177</u>	<u>42,336</u>
Deferred			
Federal	--	(1,497,464)	181,805
State	--	<u>(431,871)</u>	<u>52,464</u>
	--	<u>(1,929,335)</u>	<u>234,269</u>
Total	<u>--</u>	<u>(1,746,158)</u>	<u>276,605</u>

The actual income tax benefit differs from the expected tax computed by applying the U.S. Federal corporate tax rate of 34% to income before income tax as follows:

	<u>1999</u>	<u>2000</u>	<u>2001</u>
Computed expected tax expense	187,287	161,821	236,992
State income taxes, net of federal benefit	32,465	28,303	41,056
Foreign tax on royalty income	--	--	(7,860)
Other	<u>2,086</u>	<u>1,469</u>	<u>(8,318)</u>
Total income tax expense	221,838	191,593	261,870
Valuation allowance	(253,955)	(1,967,321)	--
Credit expiring	<u>32,117</u>	<u>29,570</u>	<u>14,735</u>
Total tax (benefit) expense	--	(1,746,158)	276,605

The Company utilized approximately \$866,000 and \$527,000 of net operating loss carryforwards to offset taxable income in fiscal years 2000 and 2001, respectively. As a result of the Company's two consecutive years of profitable results in 1999 and 2000 and the expectation of continued profitability, the Company recorded a tax benefit of approximately \$1,967,000 in fiscal 2000 as a result of the release of the valuation allowance on the deferred tax asset related to net operating loss carryforwards. The remaining valuation allowance of approximately \$154,000 and \$139,000, related to the general business credit carryforward as of December 31, 2000 and 2001, respectively, has not been released due to the uncertainty of its use before expiration. This credit expires in the years 2002 through 2006. For federal and state income tax purposes, the Company has remaining net operating loss carryforwards of approximately \$3,319,000, expiring from 2003 to 2018, that are available to offset future taxable income.

## (6) STOCKHOLDERS' EQUITY

### (a) Common Stock Purchase Warrant

In connection with a license and sublicense agreement entered into in April 2000 between the Company and Nutrition 21, Inc. covering proprietary technology relating to Nisin, the Company granted to Nutrition 21 a warrant to purchase 50,000 shares of the Company's common stock at an exercise price of \$5.29 per share. This warrant will not be exercisable unless and until the Company receives governmental approval of a product that incorporates technology covered by the license and sublicense agreement. The rights granted under the warrant will expire on the earlier of 1) April 12, 2003 if vesting has not occurred by that date or 2) the fourth anniversary of the vesting date.

### (b) Non-qualified Stock Options

In April 1992, a total of 200,000 non-qualified stock options were issued to the three, then-serving executive officers of the Company at an exercise price of \$1.05 per share, the then current market price of the Company's common stock. These options were granted outside of the stock option plans described below. Half of these options became exercisable in April 1993, and the remaining half became exercisable in April 1994. A former executive officer of the Company exercised 16,200 of such options during October 1999 and the aggregate of an additional 133,800 of such options during January and February 2000. The remaining 50,000 of such options were exercised by the two, current executive officers of the Company in January 2001.

In April 1999, a total of 93,300 non-qualified stock options were issued to the three, then-serving executive officers of the Company at an exercise price of \$1.31 per share, the then current market price of the Company's common stock. These options were granted outside of the stock option plans described below. In March 2000, 31,098 of these options became exercisable. In September 2000, 20,734 of these options terminated when one of the officers separated from the Company. In September 2001, that former officer exercised 10,300 of these options. An additional 20,734 options became exercisable in March 2001, and the remaining 20,734 options became exercisable in March 2002. If not exercised, the 62,200 remaining outstanding options expire in April 2009.

(c) Stock Option Plans

In May 1989, the stockholders approved the 1989 Stock Option and Incentive Plan (the "1989 Employee Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees may be granted options to purchase shares of the Company's common stock at i) no less than fair market value on the date of grant in the case of incentive stock options and ii) no less than 85% of fair market value on the date of grant in the case of non-qualified stock options. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case by case basis. Originally, 90,000 shares of common stock were reserved for issuance under the 1989 Employee Plan; the stockholders of the Company approved an increase in this number to 190,000 shares at the August 1992 Annual Meeting and a further increase in this number to 290,000 shares at the June 1994 Annual Meeting and a further increase in this number to 340,000 shares at the June 1998 Annual Meeting. All options granted under the 1989 Employee Plan expire no later than ten years from the date of grant. The 1989 Employee Plan expired in March 1999, and no further options may be granted under the 1989 Employee Plan; however, outstanding options under the 1989 Employee Plan may be exercised in accordance with their terms.

In June 2000, the stockholders approved the 2000 Stock Option and Incentive Plan (the "2000 Employee Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees may be granted options to purchase shares of the Company's common stock at i) no less than fair market value on the date of grant in the case of incentive stock options and ii) no less than 85% of fair market value on the date of grant in the case of non-qualified stock options. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case by case basis. 250,000 shares of common stock are reserved for issuance under the 2000 Employee Plan. All options granted under the 2000 Employee Plan expire no later than ten years from the date of grant. The 2000 Employee Plan expires in June 2010, after which date no further options may be granted under the 2000 Employee Plan; however, any outstanding options under the 2000 Employee Plan may be exercised in accordance with their terms.

In June 2000, the stockholders approved the 2000 Stock Option Plan for Outside Directors (the "2000 Outside Director Plan") pursuant to the provisions of the Internal Revenue Code of 1986. Under the 2000 Outside Director Plan, each of the five, then-serving outside directors of the Company was automatically granted a non-qualified stock option to purchase 15,000 shares of common stock at its fair market value on the date the 2000 Outside Director Plan was approved by the stockholders. Directors who are newly elected to the Board subsequent to June 2000 receive an automatic grant of an option to purchase 15,000 shares, at the fair market value on the date when such directors are first elected to the Board by the stockholders. One-third of the options subject to the grant vest on the date that the director is first re-elected to the Board by the stockholders; an additional 5,000 options vest on the second date that the director is re-elected to the Board by the stockholders; and the remaining 5,000 options vest on the third date that the director is re-elected to the Board by the stockholders. 120,000 shares of common stock are reserved for issuance under the 2000 Outside Director Plan. All options granted under the 2000 Outside Director Plan expire no later than five years from the date of grant. The 2000 Outside Director Plan expires in June 2005, after which date no further options may be granted under the 2000 Outside Director Plan; however, any outstanding options under the 2000 Outside Director Plan may be exercised in accordance with their terms.

Activity under the stock option plans described above, was as follows:

	1989 Employee Plan	1995 Outside Director Plan	2000 Employee Plan	2000 Outside Director Plan	Weighted Average Exercise Price
Balance at December 31, 1998	213,633	36,000	--	--	\$2.23
Grants	79,700	--	--	--	1.31
Terminations	(19,966)	(8,000)	--	--	1.65
Exercises	--	--	--	--	--
Balance at December 31, 1999	273,367	28,000	--	--	2.04
Grants	--	--	260,000	75,000	3.23
Terminations	(24,895)	--	(11,000)	(15,000)	2.71
Exercises	(58,300)	(28,000)	--	--	2.07
Balance at December 31, 2000	190,172	--	249,000	60,000	2.73
Grants	--	--	127,000	30,000	2.90
Terminations	(3,500)	--	(19,000)	(15,000)	2.68
Exercises	--	--	--	--	--
Balance at December 31, 2001	186,672	--	357,000	75,000	2.81
Exercisable at December 31, 2001	<u>160,738</u>	<u>--</u>	<u>31,664</u>	<u>20,000</u>	2.50

At December 31, 2001, approximately 680,935 common shares were reserved for future issuance under all outstanding stock options described above. An additional 188,000 common shares were reserved for potential issuance under future stock option grants.

(d) Compliance with Statement of Financial Accounting Standard ("SFAS") No. 123

SFAS No. 123, "Accounting for Stock-Based Compensation" requires a fair value based method of accounting for employee and director stock options and would result in expense recognition for the Company's stock plans. It also permits a Company to continue to measure compensation expense for such plans using the intrinsic value based method as prescribed by Accounting Principles Board Opinion No. 25 ("APB No. 25"), "Accounting for Stock Issued to Employees". The Company has elected to follow APB No. 25 in accounting for its stock plans, and accordingly, no compensation cost has been recognized.

Had compensation cost for the Company's stock plans been determined based on the fair value requirements of SFAS No. 123, the Company's net income and basic net income per share would have been reduced to the pro forma amounts indicated below:

		1999	2000	2001
Net income	As reported	\$550,843	\$2,222,046	\$420,435
	Pro forma	\$464,163	\$1,999,857	\$379,307
Basic net income per share	As reported	\$0.23	\$0.84	\$0.15
	Pro forma	\$0.19	\$0.76	\$0.14

The weighted average remaining life of the options outstanding under the 1989 Employee Plan, the 2000 Employee Plan and the 2000 Outside Director Plan as of December 31, 2001 was approximately seven years and one month. The exercise price of the options outstanding and of the options exercisable as of December 31, 2001 ranged from \$1.31 to \$4.00. The weighted-average grant date fair values of options granted during 2000 and 2001 were \$0.66 and \$0.44 per share, respectively. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	<u>1999</u>	<u>2000</u>	<u>2001</u>
Risk-free interest rate	5.8%	5.5%	4.2%
Dividend yield	0	0	0
Expected volatility	76.2%	45.6%	45.8%
Expected life	5 years	3 years	2.5 years

**(e) Common Stock Rights Plan**

In September 1995, the Board of Directors of the Company adopted a Common Stock Rights Plan and declared a dividend of one common share purchase right (a "Right") for each of the then outstanding shares of the common stock of the Company. Each Right entitles the registered holder to purchase from the Company one share of common stock at an initial purchase price of \$70.00 per share, subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement between the Company and American Stock Transfer & Trust Co., as Rights Agent.

The Rights become exercisable and transferable apart from the common stock upon the earlier of (i) 10 days following a public announcement that a person or group (acquiring person) has, without the prior consent of the Continuing Directors (as such term is defined in the Rights Agreement), acquired beneficial ownership of 15 percent or more of the outstanding common stock, or (ii) 10 days following commencement of a tender offer or exchange offer the consummation of which would result in ownership by a person or group of 20% or more of the outstanding common stock (the earlier of such dates being called the "Distribution Date").

Upon the acquisition of 15% or more of the Company's common stock by an acquiring person, the holder of each Right not owned by the acquiring person would be entitled to purchase common stock having a market value equal to two times the exercise price of the Right (i.e., at a 50 percent discount). If, after the Distribution Date, the Company should consolidate or merge with any other entity and the Company were not the surviving company, or, if the Company were the surviving company, all or part of the Company's common stock were changed or exchanged into the securities of any other entity, or if more than 50% of the Company's assets or earning power were sold, each Right would entitle its holder to purchase, at the Rights' then-current purchase price, a number of shares of the acquiring company's common stock having a market value at that time equal to twice the Right's exercise price.

At any time after a person or group becomes an acquiring person and prior to the acquisition by such person or group of 50% or more of the outstanding common stock, the Board of Directors of the Company may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one share of common stock per Right (subject to adjustment).

At any time prior to fourteen days following the date that any person or group becomes an acquiring person (subject to extension by the Board of Directors), the Board of Directors of the Company may redeem the then outstanding Rights in whole, but not in part, at a price of \$.005 per Right, subject to adjustment. The Rights will expire on the earlier of (i) the close of business on September 19, 2005, or (ii) the time at which the Rights are redeemed by the Company.

**(7) COMMITMENTS AND CONTINGENCIES**

The Company has entered into employment contracts with its two executive officers which could require the Company to pay three months' salary as severance pay depending upon the circumstances of any termination of employment of these key employees.

In 1998, the Company entered into a renewal of its service and license agreement effective through December 31, 2003 with Kamar, Inc. whereby Kamar will continue to provide the Company warehousing, distribution and certain other services and the Company will continue to market a certain bovine heat detection device under an exclusive worldwide license. The renewal agreement was initially cancelable by either party upon twelve months written notice. In September 2000, this license was extended by one year to December 31, 2004, and the right of Kamar to cancel early without cause was eliminated. The Company is committed to pay Kamar a monthly fee for distribution services and related license fees of approximately \$22,000 (adjusted annually for inflation) until the license agreement terminates. Royalties paid to Kamar on sales made during the years ended December 31, 1999, 2000 and 2001 were \$228,000, \$389,000 and \$664,000, respectively.

The research, manufacturing and marketing of human and animal health care products by the Company entail an inherent risk that liability claims will be asserted against the Company. The Company feels it has adequate levels of liability insurance to support its operations.

(8) SEGMENT AND SIGNIFICANT CUSTOMER INFORMATION

The Company principally operates in the business segment described in Note 1. The Company's primary customers for the majority of its product sales (74%, 76% and 76% for the years ended December 31, 1999, 2000 and 2001, respectively) are in the U.S. dairy and beef industry. Revenues derived from foreign customers, who are also in the dairy and beef industry, aggregated 24%, 22% and 22% of the Company's total product sales for the years ended December 31, 1999, 2000 and 2001, respectively. Grant and technology licensing income amounted to approximately 4% (\$187,000), 2% (\$96,000) and 3% (\$178,000) of total revenues in the years ended December 31, 1999, 2000 and 2001, respectively.

Pursuant to SFAS No. 131, the Company operates in two reportable segments: (1) Animal Health Products and (2) Research and Development ("R&D"). The accounting policies of the segments are the same as those described in Note 2, "Summary of Significant Accounting Policies." The Company evaluates the performance of its segments and allocates resources to them based on contribution before allocation of corporate overhead charges. The table below presents information about reported segments for the years ending December 31 (in thousands):

	Animal Health			
<u>Fiscal 1999:</u>	<u>Products</u>	<u>R&amp;D</u>	<u>Other</u>	<u>Total</u>
Product sales	\$4,656	--	\$ 67	\$4,723
Grant income	--	<u>\$ 187</u>	--	<u>187</u>
Total revenues	4,656	187	67	4,910
Product costs	2,124	--	29	2,153
Research and development	--	813	--	813
Sales and marketing expenses	890	--	--	890
Other expenses, net	--	--	<u>503</u>	<u>503</u>
Income (loss) before taxes	1,642	(626)	(465)	551
Tax expense	--	--	--	--
Net income (loss)	<u>\$1,642</u>	<u>\$(626)</u>	<u>\$(465)</u>	<u>\$ 551</u>

	Animal Health			
<u>Fiscal 2000:</u>	<u>Products</u>	<u>R&amp;D</u>	<u>Other</u>	<u>Total</u>
Product sales	\$5,362	--	\$ 122	\$5,484
Grant income	--	\$ 96	--	96
Royalty income	--	--	<u>55</u>	<u>55</u>
Total revenues	5,362	96	177	5,635
Product costs	2,729	--	72	2,801
Research and development	--	922	--	922
Sales and marketing expenses	1,003	--	--	1,003
Other expenses, net	--	--	<u>433</u>	<u>433</u>
Income (loss) before taxes	1,630	(826)	(328)	476
Tax benefit	--	--	<u>1,746</u>	<u>1,746</u>
Net income (loss)	<u>\$1,630</u>	<u>\$(826)</u>	<u>\$1,418</u>	<u>\$2,222</u>



<u>Fiscal 2001:</u>	<u>Animal Health</u> <u>Products</u>	<u>R&amp;D</u>	<u>Other</u>	<u>Total</u>
Product sales	\$6,261	--	\$ 134	\$6,395
Grant income	--	\$ 133	--	133
Royalty income	--	--	79	79
Technology licensing income	--	45	--	45
Sale of option to technology	--	--	25	25
Total revenues	6,261	178	238	6,677
Product costs	3,169	--	46	3,215
Research and development	--	849	--	849
Sales and marketing expenses	1,359	--	--	1,359
Other expenses, net	--	--	557	557
Income (loss) before taxes	1,733	(671)	(365)	697
Tax expense	--	--	277	277
Net income (loss)	<u>\$1,733</u>	<u>\$(671)</u>	<u>\$(642)</u>	<u>\$ 420</u>

(9) EMPLOYEE BENEFITS

The Company has a 401(k) savings plan in which all employees completing one year of service with the Company (working at least 1,000 hours) are eligible to participate. Participants may contribute up to 20% of their annual compensation to the plan, subject to certain limitations. Beginning January 1, 1994, the Company matched 50% of each employee's contribution to the plan up to a maximum match of 3% of each employee's base compensation. Under this matching contribution program, the Company paid approximately \$18,000 and \$20,000 to the plan for the years ended December 31, 1999 and 2000, respectively. Beginning January 1, 2001, the Company increased this matching contribution to 50% of each employee's contribution to the plan up to a maximum match of 4% of each employee's base compensation. Under this matching contribution program, the Company paid approximately \$29,000 to the plan for the year ended December 31, 2001.

(10) UNAUDITED QUARTERLY FINANCIAL DATA

The following tables present the quarterly information for fiscal years 2000 and 2001 (in thousands, except per share amounts):

<u>Fiscal 2000:</u>	<u>March 31</u>	<u>Fiscal Quarters Ended</u> <u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Total revenues	\$1,447	\$1,459	\$1,138	\$1,592
Income (loss) before taxes	227	64	(13)	198
Net income (loss)	227	64	(13)	1,944 *
Net income (loss) per common share:				
Basic	\$0.09	\$0.02	\$(0.01)	\$0.74
Diluted	\$0.08	\$0.02	\$(0.01)	\$0.70

\*See Note 5 for description of deferred tax valuation reserve release.

<u>Fiscal 2001:</u>	<u>March 31</u>	<u>Fiscal Quarters Ended</u> <u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Total revenues	\$1,489	\$1,837	\$1,388	\$1,964
Income (loss) before taxes	193	175	(80)	410
Net income (loss)	116	105	(57)	255
Net income (loss) per common share:				
Basic	\$0.04	\$0.04	\$(0.02)	\$0.09
Diluted	\$0.04	\$0.04	\$(0.02)	\$0.09

IMMUCELL CORPORATION AND SUBSIDIARY

SCHEDULE 2-SUPPLEMENTAL VALUATION AND QUALIFYING ACCOUNTS

Allowance for Doubtful Accounts:

Balance at December 31, 1998	44,000
Amount Charged to Costs and Expenses	--
Write-offs	(3,000)
	<hr/>

Balance at December 31, 1999	41,000
Amount Charged to Costs and Expenses	--
Write-offs	(2,000)
	<hr/>

Balance at December 31, 2000	39,000
Amount Charged to Costs and Expenses	--
Write-offs	(1,000)
	<hr/>

Balance at December 31, 2001	38,000
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### *Signatures*

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

#### IMMUCELL CORPORATION

Date: March 22, 2002

By: /s/ Michael F. Brigham  
Michael F. Brigham  
President, Chief Executive Officer and  
Treasurer

#### POWER OF ATTORNEY

We, the undersigned directors and officers of ImmuCell Corporation hereby severally constitute and appoint Michael F. Brigham our true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for us and in our stead, in any and all capacities, to sign any and all amendments to this report and all documents relating thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing necessary or advisable to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Date: March 22, 2002

By: /s/ Michael F. Brigham  
Michael F. Brigham  
President, Chief Executive Officer,  
Treasurer and Director

Date: March 22, 2002

By: /s/ Anthony B. Cashen  
Anthony B. Cashen, Director

Date: March 22, 2002

By: /s/ Joseph H. Crabb  
Joseph H. Crabb, Ph.D., Director

Date: March 22, 2002

By: /s/ Keith N. Haffer  
Keith N. Haffer, Ph.D., Director

Date: March 22, 2002

By: /s/ William H. Maxwell  
William H. Maxwell, M.D., Director

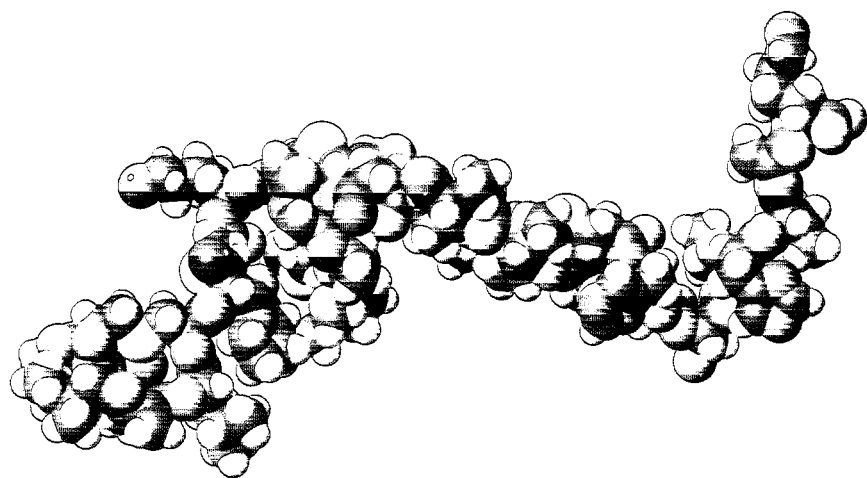
Date: March 22, 2002

By: /s/ Jonathan E. Rothschild  
Jonathan E. Rothschild, Director

Date: March 22, 2002

By: /s/ Mitchel Sayare  
Mitchel Sayare, Ph.D., Director

IMMUCELL CORPORATION  
56 EVERGREEN DRIVE  
PORTLAND, MAINE 04103



*“...to benefit our employees and shareholders through innovative and proprietary products that improve animal health and productivity in the dairy and beef industry...”*

# CORPORATE INFORMATION

## **Executive Officers**

Michael F. Brigham:	President and Chief Executive Officer, Treasurer and Secretary
Joseph H. Crabb, Ph.D.:	Vice President and Chief Scientific Officer

## **Board of Directors**

Michael F. Brigham:	President and Chief Executive Officer, Treasurer and Secretary
Anthony B. Cashen:	Retired Senior Partner, TMP Worldwide, Inc., New York, NY
Joseph H. Crabb, Ph.D.:	Vice President and Chief Scientific Officer
William H. Maxwell, M.D.:	President, Maxwell, Knowland and Kluger, M.D., P.A., Portland, ME
Jonathan E. Rothschild:	President, Arterio, Inc., Concord, CA
Mitchel Sayare, Ph.D.:	Chairman and CEO, ImmunoGen, Inc., Cambridge, MA

## **Legal Counsel**

Day, Berry & Howard LLP, Boston, MA

## **Independent Accountants**

PricewaterhouseCoopers LLP, Portland, ME

## **Banking Relationship**

Peoples Heritage Bank, Portland, ME

## **Registrar and Transfer Agent**

American Stock Transfer and Trust Co., Brooklyn, NY

## **Common Stock**

Listed on The Nasdaq SmallCap Market  
under the symbol: ICCG

## **Corporate Headquarters**

ImmuCell Corporation  
56 Evergreen Drive  
Portland, ME 04103  
Phone: (207) 878-2770  
Fax: (207) 878-2117

*Inside pocket artwork: model of Nisin, courtesy of Dr. Eeffjan Breukink  
of the University of Utrecht, The Netherlands.*

*Back cover artwork: computer model of IgG antibody, courtesy of Dr. David R. Davies  
of the National Institutes of Health.*

## **ANNUAL REPORT**

This year's annual report is simply the Company's Form 10-K for the fiscal year ended December 31, 2001, which provides all financial and other information on the Company, enclosed inside a descriptive pocket cover.

For current information about ImmuCell, please visit our corporate web site at [www.immucell.com](http://www.immucell.com).